

EPA Registration No.
39967-137
Vol. 8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 4 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Susan M. Schaner
E.I. du Pont de Nemours and Company
Dupont Chemicals & Fluoroproducts,
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon(R) S**
EPA Registration Number: 71654-6
Application Date: March 31, 2011
Receipt Date: April 5, 2011

Dear Ms. Schaner:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable.

Proposed Amendment

- Updating Label per Agency Letter Dated 7/15/10 and Meeting on 3/30/11

General Comments

Submit 3 copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 308-6440 or by email at grigsby.stacey@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

Stacey Grigsby
#1 Jacqueline Campbell-McFarlane
Product Manager 34

Regulatory Management Branch II
Antimicrobials Division (7510P)

| | | | | | | | |
|---------|--------------------------|--|--|--|--|--|--|
| SYMBOL | Enclosure: stamped label | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

Virkon® S
Disinfectant and Virucide

[BROAD SPECTRUM DISINFECTANT,][FUNGICIDE] [& ALGAECIDE] OPT

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] [OPT]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
[For Use in Emergency Disease Control] OPT]

Effective against

Viruses

Including Canine Parvovirus [OPT]

Bacteria

Fungi

ACTIVE INGREDIENTS:

Potassium peroxymonosulfate..... 21.41%

Sodium Chloride..... 1.50%

OTHER INGREDIENTS..... 77.09%

TOTAL..... 100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO

[See Inside Booklet for Additional Precautions] [OPT]

[See leaflet for additional directions for use] [OPT]

EPA Reg. No. 71654-6

EPA Est. No. XXXXX-YY-ZZZ

<Lot or batch #>

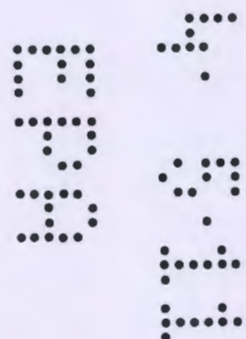
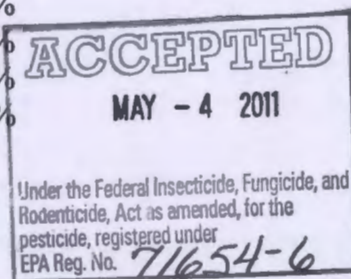
[POWDER FORM] [OPT]

[TABLET FORM] [OPT]

[SACHET FORM] [OPT]

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Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company



Front Panel Continued

| FIRST AID | |
|---|---|
| If in Eyes: | <p>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</p> <p>Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.</p> <p>Call a Poison Control Center or doctor for further treatment advice.</p> |
| If on Skin or Clothing: | <p>Take off contaminated clothing.</p> <p>Rinse skin immediately with plenty of water for 15-20 minutes.</p> <p>Call a Poison Control Center or doctor for further treatment advice.</p> |
| If Swallowed: | <p>Call a Poison Control Center or doctor immediately for treatment advice.</p> <p>Have person sip a glass of water if able to swallow.</p> <p>Do not induce vomiting unless told to do so by the poison control center or doctor</p> <p>Do not give anything by mouth to an unconscious person</p> |
| HOT LINE NUMBER | |
| <p>For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> | |
| <p>Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.</p> | |

Manufactured for:
 E.I. DuPont de Nemours and Company
 PO Box 80402
 Wilmington, DE 19880-0402
 Questions? Call 1-800-441-7515
 Outside the US, contact: 1-302-774-1000

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING [PATHOGEN]: OPT

[ANIMAL AND ZOONOTIC PATHOGENS] OPT

BACTERIA

[Actinobacillus pleuropneumoniae] OPT

[Bacillus cereus] OPT

[Brucella abortus] OPT

[Campylobacter jejuni] OPT

[Clostridium perfringens]

[Dermatophilus congolensis]

[Escherichia coli]

[Klebsiella pneumoniae]

[Mycoplasma gallisepticum]

[Mycoplasma hyopneumonia]

[Pasteurella multocida] OPT

Pseudomonas aeruginosa

Salmonella enterica

Salmonella typhimurium

[Shigella sonnei] OPT

[Staphylococcus aureus]

[Staphylococcus epidermidis]

[Streptococcus pyogenes]

[Streptococcus suis]

[Not approved in California for use against the following bacteria:]

[Bordetella avium]

[Bordetella bronchiseptica]

]Fistulous withers (Poll Evil)]

[Haemophilus somnus]

[Helicobacter pylori]

[Listeria monocytogenes]

[Moraxella bovis (Pink Eye)]

[Mycoplasma mycoides]

[Pseudomonas mallei (Glanders)]

[Pseudomonas vulgaris]

[Streptococcus equi (Strangles)]

[Taylorella equigenitalis]

[Treponema hyodysenteriae] OPT

VIRUSES

Avian Influenza Virus

[Avian Laryngotracheitis Virus] OPT

[Bovine Adenovirus Type 4]

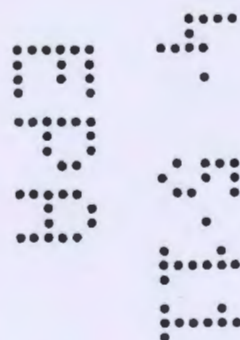
[Canine Adenovirus (Canine Hepatitis)] OPT



[Canine Parvovirus] OPT
 [Equine Herpes Virus (Type 1)]
 [Equine Herpes Virus (Type 3)]
 [Equine Influenza Virus (Type A)]
 [Feline Calicivirus]
 [Feline Panleukopenia Virus]
 [Feline Rhinotracheitis Virus]
 [Newcastle Disease Virus]
 [Simian virus (SV40 Virus)]

[Not approved in California for use against the following viruses:]

[Adenovirus Pneumonia]
 [African Horse Sickness Virus]
 [African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)]
 [Bovine Polyoma Virus]
 [Bovine Pseudocowpox Virus]
 [Bovine Viral Diarrhea Virus (no hard water)]
 [Calf Rotavirus (no hard water)]
 [Canine Coronavirus]
 [Canine Parainfluenza Virus]
 [Chicken Anemia Virus]
 [Coital Exanthema Virus]
 [Distemper Virus]
 [Duck Adenovirus (no hard water)]
 [Duck Enteritis Virus]
 [Egg Drop Syndrome Adenovirus]
 [Equine Infectious Anemia Virus (Swamp Fever)]
 [Equine Arteritis Virus (no hard water)]
 [Equine Contagious Abortion Virus]
 [Equine Papillomatosis Virus]
 [Equine Influenza Virus (The Cough)]
 [Feline Herpes Virus]
 [Feline Infectious Peritonitis Virus]
 [Feline Parvovirus]
 [Foot and Mouth Disease Virus]
 [Hog Cholera Virus]
 [Infectious Bronchitis Virus]
 [Infectious Bursal Disease Virus]
 [Infectious Canine Hepatitis Virus]
 [Infectious Pancreatic Necrosis Virus]
 [Infectious Salmon Anaemia Virus]
 [Infective Bovine Rhinotracheitis Virus (no hard water)]
 [Leptospira Canicola Virus]
 [Maedi- Visna Virus]
 [Marek's Disease Virus]
 [Mouse Parvovirus]
 [PCV2 Virus (PMWS)]
 [Porcine Parvovirus]
 [Porcine Reproductive and Respiratory Syndrome Virus (PRRS)] OPT



[Pseudorabies Virus (Aujeszky's Disease) (no hard water)] OPT
[Rotaviral Diarrhea Virus]
[Snakehead rhabdovirus]
[Swine Influenza Virus]
[Swine Vesicular Disease Virus]
[Transmissible Gastroenteritis Virus (TGE) (no hard water)]
[Turkey Herpes Virus (no hard water)]
[Turkey Rhinotracheitis Virus]
[Vesicular Stomatitis Virus]

[FUNGI]

[Trichophyton mentagrophytes (2%)]

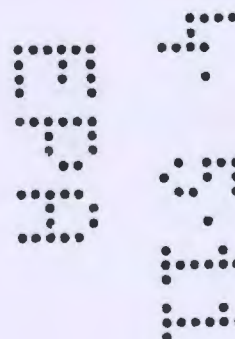
[Not approved in California for use against the following fungi:]

[Aspergillus fumigatus]
[Fusarium moniliforme]
[Microsporum canis]
[Trichophyton spp. (Ringworm)]
[Trichophyton spp. (Mud Fever)]

[PLANT PATHOGENS]

[Not approved in California for use against plant pathogens:]

[Alternaria solani]
[Botrytis cinera]
[Colletotrichum coccodes]
[Didymella bryoniae]
[Fusarium oxysporum]
[Fusarium solani]
[Penicillium oxalicum]
[Phomopsis sclerotoides]
[Pyrenochaeta lycoopersici]
[Pythium aphanidermatum]
[Rhizoctonia solani]
[Sclerotinia sclerotiorum]
[Thielaviopsis basicola]
[Verticillium dahliae]
[Xanthomonas axonopodis] OPT



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use-diluted solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts – Not Approved for this use in California), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., “no hard water,” “no soil load,” and “use 2% solution.”

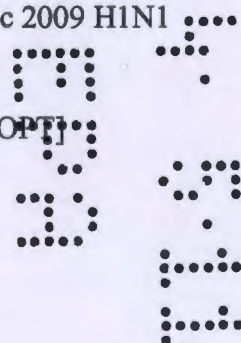
[Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Virkon® S [OPT] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).] [OPT]

[This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.] [OPT]

[This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).] [OPT]

[Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).] [OPT]

[Kills Pandemic 2009 H1N1 influenza A virus.] [OPT]



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

[Fogging (Wet Misting) Instructions –

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

Close room off, so fog is confined to room to be treated.

Prepare a Virkon® S dilution of 0.5% to 2.0% in water (1:200 to 1:50) - (refer to specific directions for Poultry, Swine, Bovine, Greenhouse and Aquaculture uses.).

Apply use-diluted solution at an application rate of 1 gallon per 430 ft² of floor space. Use a mechanical or plumbed in misting system designed for water-based applications with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer, to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.

Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves, and pants.] OPT.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water.] OPT.

Powder

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|--------------|
| 1 Quart | 0.15 ounces* | 0.3 ounces | 0.7 ounces |
| 1 Gallon | 0.65 ounces* | 1.3 ounces | 2.7 ounces |
| 10 Gallons | 6.7 ounces* | 13.4 ounces | 26.7 ounces |
| 50 Gallons | 33.4 ounces* | 66.8 ounces | 133.5 ounces |

Measuring cup provided.

Tablet

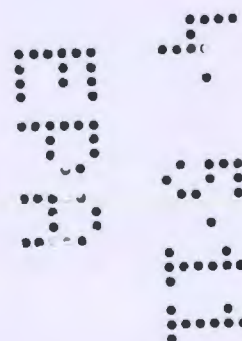
| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|-------------|
| 1 Pint | | 1 tablet | 2 tablets |
| 1 Quart | 1 tablet* | 2 tablets | 4 tablets |
| 1 Gallon | 4 tablets* | 8 tablets | 16 tablets |

Sachet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|-------------|
| 1 gallon | - | 1 Sachet | 2 Sachets |
| 2 Gallons | 1 Sachet | 2 Sachets | 4 Sachets |

* The 0.5% solution currently is not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]



[POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Mycoplasma gallisepticum*. Not approved in California for use against the following organisms: Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts – Not Approved for this use in California) *Aspergillus flavus*, Fungi of *Aspergillus fumigatus* and Bacteria of *Bordetella avium*, *Helicobacter pylori*.] OPT.

[HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.] OPT.

[Fogging (Wet Misting) Instructions – Poultry and Ratite Production

Follow General Instructions to remove poultry and/or animals from room to be treated.

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

Close room off, so fog is confined to room to be treated.

Prepare a Virkon® S at dilution of 1.0% to 2.0% in water (1:100 to 1:50).

Apply at an application rate of 1 gallon per 430 ft² of floor space. Use a mechanical or plumbed in misting system designed for water-based applications with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.

Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves, and pants.] OPT.

[BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with potable water. Do not house poultry or use equipment until treatment has dried.] OPT

[PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry.] OPT.

[SWINE PRODUCTION] OPT.

[CONTROLS: Bacteria of; Actinobacillus Pleuropneumoniae and Clostridium perfringens; Fungi of Trichophyton mentragrophytes (2%). Not approved in California for use against the following organisms: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme, Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.] OPT.

[Follow General Instructions to remove swine and preclean area to be treated. Use a 1% solution of Virkon® S for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.] OPT.

[Fogging (Wet Misting) --- Swine

Follow General Instructions to remove poultry and/or animals from room to be treated.

Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[EQUINE PRODUCTION] OPT.

[BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES AND EQUIPMENT] OPT

[CONTROLS: Viruses of Equine herpes virus Type 1 and Type 3 and Equine Influenza. Bacteria of; Brucella abortus, Clostridium perfringens, Dermatophilus congolensis (at 2%), Pseudomonas aeruginosa, Salmonella typhimurium and Staphylococcus aureus. Fungi of Trichophyton mentragrophytes (at 2%). Not approved in California for use against the following organisms: Fungi of Fusarium moniliforme, Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial

Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).] OPT.

[APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Follow general instructions to remove animals from area to be treated. Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution, saturating surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[To Clean Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Using a 1% solution of Virkon® S, Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.] OPT

[BOVINE PRODUCTION] OPT.

[CONTROLS: Bovine Adenovirus Type 4; Fungi of Trichophyton mentragrophytes(2%). Not approved in California for use against the following organisms: Bacteria of Moraxella bovis and Fungi of Fusarium moniliforme. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of Haemophilus somnus.] OPT.

[Follow General Instructions to remove livestock and preclean area to be treated. Use a 1% solution of Virkon® S to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.] OPT.

[Fogging (Wet Misting) --- Bovine

Follow General Instructions to remove poultry and/or animals from room to be treated.

Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[COMPANION ANIMALS] OPT.

[CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa. Fungi of Trichophyton mentragrophytes(2%). Not approved in California for use against the following organisms: Viruses of Distemper, Leptospira canicola, Feline parvovirus, Feline herpes; Fungi of Microsporum canis.] OPT.

[APPLICATIONS: Use a 1% solution of Virkon® S as a “one step” cleaning and disinfecting procedure (Remove gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, animal infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.] OPT.

[GREENHOUSES AND HORTICULTURE] OPT.

[Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. Not approved in California for use on ventilation and other equipment and water systems. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.] OPT.

[For surfaces and equipment

- 1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.
- 2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to remove organic deposits.
- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water.

Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.] OPT.

[For evaporative coolers: Not approved use in California: Treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.] OPT.

[Virkon® S may also be used to disinfect irrigation tanks and lines. Not approved use in California: Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.] OPT.

[Fogging (Wet Misting) Instructions – Greenhouse/Horticulture

[Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[AQUACULTURE] OPT.

[Not approved for this use in California] OPT.

[Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.] OPT.

[Equipment used in separate sites, tanks, ponds in aquaculture settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.] OPT.

[Fogging (Wet Misting) Instructions -- Aquaculture

Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)] OPT.

[Not approved for this use in California] OPT.

[Disinfection helps to control and prevent the cross-contamination of OIE List A organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia).] OPT.

[Use a 1% solution of Virkon® S to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.] OPT.

[DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISM PCV2 VIRUS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection. However, Virkon® S is an effective disinfectant for all hard, non-porous surfaces against the following organism at the dilution rates specified below. If the threat is known and limited to one of the organism below, Virkon® S may be used at the following dilution rates:] OPT

| [Organism] | Dilution Rate | Oz./Gal. |
|-------------------|------------------|----------|
| PCV2 Virus (PMWS) | 1:200 | 0.7] OPT |

[USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS] OPT.

[Use a 1% solution of Virkon® S to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or

allowing people to contact treated sites.] OPT.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant canister with product during storage.]

Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children.

[Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

[For spray bottle with in-use solution: Store in a cool dry place. Keep out of reach of children.

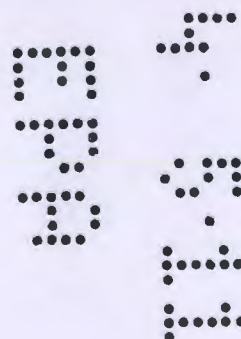
Do not mix this product with other chemicals.]

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.

[Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles.

Empty residue into application equipment.] Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 7, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THOMAS C. MCENTEE
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

PRODUCT NAME: VIRKON S
COMPANY NAME: E.I. DUPONT DE NEMOURS AND COMPANY
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 71654-6
EPA RECEIPT DATE: 04/05/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6416.

Sincerely,

P. K. Thorne

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Receipt for Section 3

S: 893290

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY

V

Risk Manager: Antimicrobiols Division, Risk Management Team 34


Product #: 71654-6


Product Name: VIRKON S


Override#:


Me Too Section3:

Me Too Product Name:

Application Date: 31-Mar-2011 

OPP Rec'vd Date: 05-Apr-2011 

Front End Date: 05-Apr-2011 

Risk Manager Send Date: 07-Apr-2011 

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description: Label amendment

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

| Receipt Content | Des |
|------------------|-----|
| Paper Label | |
| Electronic Label | |

<

01

>

View/Edit

Fee for Service

{893290,~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr.

34

Receipt No.

S-

893290

EPA File Symbol/Reg. No.

71654-6

Pin-Punch Date:

4/5/2011



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team 1

Date: 4/6/11

Remarks:

| | | | |
|---|--|--|--|
| United States Environmental Protection Agency Washington, DC 20460 | | <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other | OPP Identifier Number |
| Application for Pesticide - Section I | | | |
| 1. Company/Product Number 71654-6 | | 2. EPA Product Manager Jacqueline Campbell-McFarlane | |
| 4. Company/Product (Name) Virkon(R) S | | PM# 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company Attn: Susan Schaner Dupont Chemicals & Fluoroproducts, P. O. Box 80402 Wilmington, DE 19880-0402 | | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted | |
| <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |
| Section - II | | | |
| <input checked="" type="checkbox"/> Amendment - Explain below. | | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ | |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | | <input type="checkbox"/> "Me Too" Application. | |
| <input type="checkbox"/> Notification - Explain below. | | <input type="checkbox"/> Other - Explain below. | |
| Explanation: Use additional page(s) if necessary. (For section I and Section II.) Amended labeling - Submitted in response to Accepted-With-Comments letter of July 15, 2010 and meeting of March 30, 2011. E-Label Master. | | | |
| Section - III | | | |
| 1. Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper Other (Specify) _____ |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. No. per container | If "Yes" Package wgt No. per container |
| | | 1.3 oz. | 50 |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 10 lb., 4 lb, 1lb., 9 oz., | |
| | | 5. Location of Label Directions <input checked="" type="checkbox"/> | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled | | <input type="checkbox"/> Other _____ | |
| Section - IV | | | |
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name | Title | Telephone No. (Include Area Code) | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received (Stamped) |
| 2. Signature | | 3. Title Regulatory Coordinator | |
| 4. Typed Name Susan M. Schaner | | 5. Date March 31, 2011 | |

Virkon® S
Disinfectant and Virucide

[BROAD SPECTRUM DISINFECTANT,][FUNGICIDE] [& ALGAECIDE] OPT

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] [OPT]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
[For Use in Emergency Disease Control] OPT]

Effective against

Viruses

Including Canine Parvovirus [OPT]

Bacteria

Fungi

ACTIVE INGREDIENTS:

| | |
|----------------------------------|---------|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO

[See Inside Booklet for Additional Precautions] [OPT]

[See leaflet for additional directions for use] [OPT]

EPA Reg. No. 71654-6

EPA Est. No. XXXXX-YY-ZZZ

<Lot or batch #>

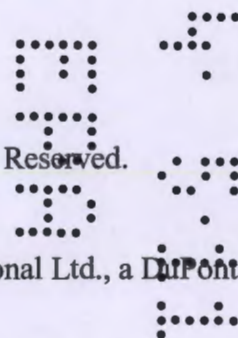
[POWDER FORM] [OPT]

[TABLET FORM] [OPT]

[SACHET FORM] [OPT]

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Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company



Front Panel Continued

| FIRST AID | |
|---|---|
| If in Eyes: | <p>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</p> <p>Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.</p> <p>Call a Poison Control Center or doctor for further treatment advice.</p> |
| If on Skin or Clothing: | <p>Take off contaminated clothing.</p> <p>Rinse skin immediately with plenty of water for 15-20 minutes.</p> <p>Call a Poison Control Center or doctor for further treatment advice.</p> |
| If Swallowed: | <p>Call a Poison Control Center or doctor immediately for treatment advice.</p> <p>Have person sip a glass of water if able to swallow.</p> <p>Do not induce vomiting unless told to do so by the poison control center or doctor</p> <p>Do not give anything by mouth to an unconscious person</p> |
| HOT LINE NUMBER | |
| <p>For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> | |
| <p>Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.</p> | |

Manufactured for:

E.I. DuPont de Nemours and Company

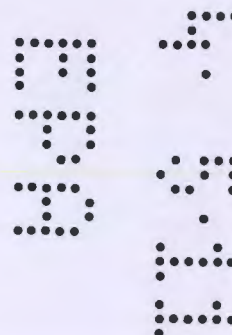
PO Box 80402

Wilmington, DE 19880-0402

Questions? Call 1-800-441-7515

Outside the US, contact: 1-302-774-1000

US Patent No. 4822512



EFFECTIVE AGAINST THE FOLLOWING [PATHOGEN]: OPT

[ANIMAL AND ZOONOTIC PATHOGENS] OPT

BACTERIA

[Actinobacillus pleuropneumoniae] OPT

[Bacillus cereus] OPT

[Brucella abortus] OPT

[Campylobacter jejuni] OPT

[Clostridium perfringens]

[Dermatophilus congolensis]

[Escherichia coli]

[Klebsiella pneumoniae]

[Mycoplasma gallisepticum]

[Mycoplasma hyopneumonia]

[Pasteurella multocida] OPT

Pseudomonas aeruginosa

Salmonella enterica

Salmonella typhimurium

[Shigella sonnei] OPT

[Staphylococcus aureus]

[Staphylococcus epidermidis]

[Streptococcus pyogenes]

[Streptococcus suis]

[Not approved in California for use against the following bacteria:]

[Bordetella avium]

[Bordetella bronchiseptica]

[Fistulous withers (Poll Evil)]

[Haemophilus somnus]

[Helicobacter pylori]

[Listeria monocytogenes]

[Moraxella bovis (Pink Eye)]

[Mycoplasma mycoides]

[Pseudomonas mallei (Glanders)]

[Pseudomonas vulgaris]

[Streptococcus equi (Strangles)]

[Taylorella equigenitalis]

[Treponema hyodysenteriae] OPT

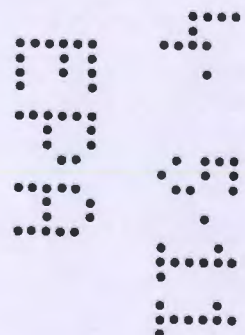
VIRUSES

Avian Influenza Virus

[Avian Laryngotracheitis Virus] OPT

[Bovine Adenovirus Type 4]

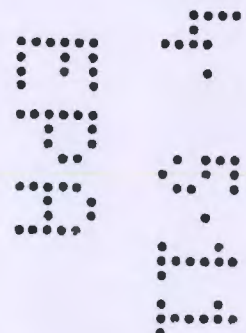
[Canine Adenovirus (Canine Hepatitis)] OPT



[Canine Parvovirus] OPT
 [Equine Herpes Virus (Type 1)]
 [Equine Herpes Virus (Type 3)]
 [Equine Influenza Virus (Type A)]
 [Feline Calicivirus]
 [Feline Panleukopenia Virus]
 [Feline Rhinotracheitis Virus]
 [Newcastle Disease Virus]
 [Simian virus (SV40 Virus)]

[Not approved in California for use against the following viruses:]

[Adenovirus Pneumonia]
 [African Horse Sickness Virus]
 [African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)]
 [Bovine Polyoma Virus]
 [Bovine Pseudocowpox Virus]
 [Bovine Viral Diarrhea Virus (no hard water)]
 [Calf Rotavirus (no hard water)]
 [Canine Coronavirus]
 [Canine Parainfluenza Virus]
 [Chicken Anemia Virus]
 [Coital Exanthema Virus]
 [Distemper Virus]
 [Duck Adenovirus (no hard water)]
 [Duck Enteritis Virus]
 [Egg Drop Syndrome Adenovirus]
 [Equine Infectious Anemia Virus (Swamp Fever)]
 [Equine Arteritis Virus (no hard water)]
 [Equine Contagious Abortion Virus]
 [Equine Papillomatosis Virus]
 [Equine Influenza Virus (The Cough)]
 [Feline Herpes Virus]
 [Feline Infectious Peritonitis Virus]
 [Feline Parvovirus]
 [Foot and Mouth Disease Virus]
 [Hog Cholera Virus]
 [Infectious Bronchitis Virus]
 [Infectious Bursal Disease Virus]
 [Infectious Canine Hepatitis Virus]
 [Infectious Pancreatic Necrosis Virus]
 [Infectious Salmon Anaemia Virus]
 [Infective Bovine Rhinotracheitis Virus (no hard water)]
 [Leptospira Canicola Virus]
 [Maedi- Visna Virus]
 [Marek's Disease Virus]
 [Mouse Parvovirus]
 [PCV2 Virus (PMWS)]
 [Porcine Parvovirus]
 [Porcine Reproductive and Respiratory Syndrome Virus (PRRS)] OPT



[Pseudorabies Virus (Aujeszky's Disease) (no hard water)] OPT
 [Rotaviral Diarrhea Virus]
 [Snakehead rhabdovirus]
 [Swine Influenza Virus]
 [Swine Vesicular Disease Virus]
 [Transmissible Gastroenteritis Virus (TGE) (no hard water)]
 [Turkey Herpes Virus (no hard water)]
 [Turkey Rhinotracheitis Virus]
 [Vesicular Stomatitis Virus]

[FUNGI]

[Trichophyton mentagrophytes (2%)]

[Not approved in California for use against the following fungi:]

[Aspergillus fumigatus]
 [Fusarium moniliforme]
 [Microsporum canis]
 [Trichophyton spp. (Ringworm)]
 [Trichophyton spp. (Mud Fever)]

[PLANT PATHOGENS]

[Not approved in California for use against plant pathogens:]

[Alternaria solani]
 [Botrytis cinera]
 [Colletotrichum coccodes]
 [Didymella bryoniae]
 [Fusarium oxysporum]
 [Fusarium solani]
 [Penicillium oxalicum]
 [Phomopsis sclerotioides]
 [Pyrenochaeta lycoopersici]
 [Pythium aphanidermatum]
 [Rhizoctonia solani]
 [Sclerotinia sclerotiorum]
 [Thielaviopsis basicola]
 [Verticillium dahliae]
 [Xanthomonas axonopodis] OPT

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks, shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use-diluted solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts – Not Approved for this use in California), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., “no hard water,” “no soil load,” and “use 2% solution.”

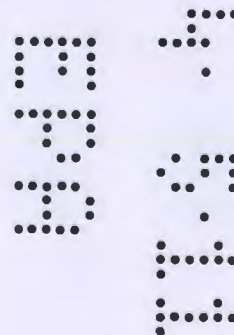
[Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Virkon® S [OPT] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).] [OPT]

[This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.] [OPT]

[This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).] [OPT]

[Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).] [OPT]

[Kills Pandemic 2009 H1N1 influenza A virus.] [OPT]



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

[Fogging (Wet Misting) Instructions –

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

Close room off, so fog is confined to room to be treated.

Prepare a Virkon® S dilution of 0.5% to 2.0% in water (1:200 to 1:50) - (refer to specific directions for Poultry, Swine, Bovine, Greenhouse and Aquaculture uses.).

Apply use-diluted solution at an application rate of 1 gallon per 430 ft² of floor space. Use a mechanical or plumbed in misting system designed for water-based applications with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.

Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves, and pants.] OPT.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water.] OPT.

Powder

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|--------------|
| 1 Quart | 0.15 ounces* | 0.3 ounces | 0.7 ounces |
| 1 Gallon | 0.65 ounces* | 1.3 ounces | 2.7 ounces |
| 10 Gallons | 6.7 ounces* | 13.4 ounces | 26.7 ounces |
| 50 Gallons | 33.4 ounces* | 66.8 ounces | 133.5 ounces |

Measuring cup provided.

Tablet

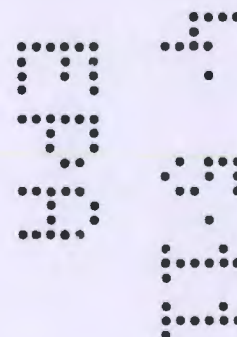
| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|-------------|
| 1 Pint | | 1 tablet | 2 tablets |
| 1 Quart | 1 tablet* | 2 tablets | 4 tablets |
| 1 Gallon | 4 tablets* | 8 tablets | 16 tablets |

Sachet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|-------------|
| 1 gallon | - | 1 Sachet | 2 Sachets |
| 2 Gallons | 1 Sachet | 2 Sachets | 4 Sachets |

* The 0.5% solution currently is not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]



[POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Mycoplasma gallisepticum*. Not approved in California for use against the following organisms: Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts – Not Approved for this use in California) *Aspergillus flavus*, Fungi of *Aspergillus fumigatus* and Bacteria of *Bordetella avium*, *Helicobacter pylori*.] OPT.

[HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatching, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.] OPT.

[Fogging (Wet Misting) Instructions – Poultry and Ratite Production

Follow General Instructions to remove poultry and/or animals from room to be treated.

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices.

Close room off, so fog is confined to room to be treated.

Prepare a Virkon® S at dilution of 1.0% to 2.0% in water (1:100 to 1:50).

Apply at an application rate of 1 gallon per 430 ft² of floor space. Use a mechanical or plumbed in misting system designed for water-based applications with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver fine mist. Insert the nozzle of the fogging device through a suitable opening in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Do not house animals or use equipment until treatment has dried. Rinse waterers and feeders with potable water before reuse. Rinse foggers and sprayers with potable water following use.

Note: Individuals must avoid entering the building or room during fogging. If the building or room must be entered, then individuals entering must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves, and pants.] OPT.

[BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with potable water. Do not house poultry or use equipment until treatment has dried.] OPT

[PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry.] OPT.

[SWINE PRODUCTION] OPT.

[CONTROLS: Bacteria of; Actinobacillus Pleuropneumoniae and Clostridium perfringens; Fungi of Trichophyton mentagrophytes (2%). Not approved in California for use against the following organisms: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of Fusarium moniliforme, Foot and Mouth Disease and Bacteria of Treponema hyodysenteriae.] OPT.

[Follow General Instructions to remove swine and preclean area to be treated. Use a 1% solution of Virkon® S for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.] OPT.

[Fogging (Wet Misting) --- Swine

Follow General Instructions to remove poultry and/or animals from room to be treated.

Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[EQUINE PRODUCTION] OPT.

[BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES AND EQUIPMENT] OPT

[CONTROLS: Viruses of Equine herpes virus Type 1 and Type 3 and Equine Influenza; Bacteria of; Brucella abortus, Clostridium perfringens, Dermatophilus congolensis (at 2%), Pseudomonas aeruginosa, Salmonella typhimurium and Staphylococcus aureus. Fungi of Trichophyton mentagrophytes (at 2%). Not approved in California for use against the following organisms: Fungi of Fusarium moniliforme, Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial

Diarrhea, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).] OPT.

[APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Follow general instructions to remove animals from area to be treated. Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution, saturating surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[To Clean Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Using a 1% solution of Virkon® S, Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.] OPT

[BOVINE PRODUCTION] OPT.

[CONTROLS: Bovine Adenovirus Type 4; Fungi of *Trichophyton mentragrophytes*(2%). Not approved in California for use against the following organisms: Bacteria of *Moraxella bovis* and Fungi of *Fusarium moniliforme*. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of *Haemophilus somnus*.] OPT.

[Follow General Instructions to remove livestock and preclean area to be treated. Use a 1% solution of Virkon® S to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.] OPT.

[Fogging (Wet Misting) --- Bovine

Follow General Instructions to remove poultry and/or animals from room to be treated.

Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with potable water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[COMPANION ANIMALS] OPT.

[CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. Fungi of *Trichophyton mentragrophytes*(2%). Not approved in California for use against the following organisms: Viruses of Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes; Fungi of *Microsporum canis*.] OPT.

[APPLICATIONS: Use a 1% solution of Virkon® S as a “one step” cleaning and disinfecting procedure (Remove gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, animal infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles. Saturate surfaces with a 1% solution of Virkon® S with a cloth, mop, mechanical spray, or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.] OPT.

[GREENHOUSES AND HORTICULTURE] OPT.

[Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. Not approved in California for use on ventilation and other equipment and water systems. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.] OPT.

[For surfaces and equipment

- 1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.
- 2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to remove organic deposits.
- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water.

Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.] OPT.

[For evaporative coolers: Not approved use in California: Treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.] OPT.

[Virkon® S may also be used to disinfect irrigation tanks and lines. Not approved use in California: Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.] OPT.

[Fogging (Wet Misting) Instructions – Greenhouse/Horticulture]

[Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with **potable** water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[AQUACULTURE] OPT.

[Not approved for this use in California] OPT.

[Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.] OPT.

[Equipment used in separate sites, tanks, ponds in aquaculture settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.] OPT.

[Fogging (Wet Misting) Instructions -- Aquaculture]

Use a 0.5% -1.0% solution of Virkon® S for fogging (wet misting) operations as a supplemental measure after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use. Refer to Fogging (Wet Misting instructions)]. OPT.

[EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)] OPT.

[Not approved for this use in California] OPT.

[Disinfection helps to control and prevent the cross-contamination of OIE List A organisms, including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia).] OPT.

[Use a 1% solution of Virkon® S to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.] OPT.

[DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISM PCV2 VIRUS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection. However, Virkon® S is an effective disinfectant for all hard, non-porous surfaces against the following organism at the dilution rates specified below. If the threat is known and limited to one of the organism below, Virkon® S may be used at the following dilution rates:] OPT

| [Organism | Dilution Rate | Oz./Gal. |
|-------------------|------------------|----------|
| PCV2 Virus (PMWS) | 1:200 | 0.7] OPT |

[USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS] OPT.

[Use a 1% solution of Virkon® S to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or

allowing people to contact treated sites.] OPT.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

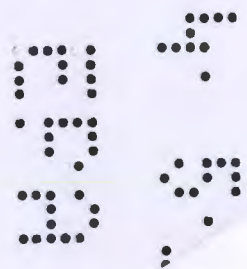
For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

[For spray bottle with in-use solution: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.

[Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.] Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.





DuPont Chemicals & Fluoroproducts

March 31, 2011

Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Jacqueline Campbell-McFarlane (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Application to Amend Labeling

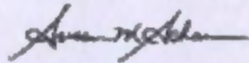
Dear Ms. Campbell-McFarlane,

Please consider this letter and attachments as our application to amend the subject registration to upgrade labeling for the subject product. Labeling has been revised in accordance with the requirements of your July 15, 2010 accepted-with comments letter, excepting the following changes which were agreed to during the March 30, 2011 meeting at your office attended by yourself, Ms. Stacey Grigbsy, Mr. Mark Hartman and Mr. Thomas McEntee (DuPont).

- 1) The Fogging (Wet Misting) Instructions are revised by deleting the statement, "Follow General Instruction ... to be treated." Also, the dilution rate has been changed to 0.5%-2.0% (with comment in parentheses to refer to specific dilution directions by end-user application).
- 2) The various animal housing facilities (poultry/swine/equine/bovine) directions have been modified to include the statement, "Follow General Instructions to remove poultry and/or animals from room to be treated."
- 3) We agreed that the phrase, "may be" under the "Pesticide Disposal" section was acceptable.
- 4) The "Blankets, Saddle Pads, and Rugs" heading has been revised by indicating "To Clean Blankets, Saddle Pads, and Rugs."
- 5.) The term, "animal," has been added to clarify the use site, "infectious disease wards."
- 6.) The statement, "Disinfection helps to control and prevent the spread of OIE List A organisms" has been revised to read: "Disinfection helps to control and prevent the cross contamination of OIE List A organisms".

Should you have any questions, feel free to call me at 302.695.2328 or e-mail me at susan.m.schaner@usa.dupont.com.

Sincerely,



Susan M. Schaner
Regulatory Coordinator
DuPont Chemicals & Fluoroproducts

Enclosures



DuPont Chemicals & Fluoroproducts

March 31, 2011

Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Jacqueline Campbell-McFarlane (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Application to Amend Labeling

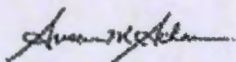
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- 5.) The term, "animal," has been added to clarify the use site, "infectious disease wards."
- 6.) The statement, "Disinfection helps to control and prevent the spread of OIE List A organisms" has been revised to read: "Disinfection helps to control and prevent the cross contamination of OIE List A organisms".

Should you have any questions, feel free to call me at 302.695.2328 or e-mail me at susan.m.schaner@usa.dupont.com.

Sincerely,



Susan M. Schaner
Regulatory Coordinator
DuPont Chemicals & Fluoroproducts

Enclosures

TRANSMITTAL DOCUMENT

Attention:

Antimicrobials Division (7510P)
Ms. Jacqueline Campbell-McFarlane
US Environmental Protection Agency
Office of Pesticide Programs
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER

E. I. du Pont de Nemours and Company
DuPont Chemicals & Fluoroproducts
Experimental Station (ESL402/3224D)
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

Amended labeling

"Virkon®" S; EPA Registration No. 71654-6

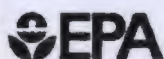
Transmittal Date: March 31, 2011

Transmittal Material:

| | | |
|----------|---|-----------|
| Volume 1 | Administrative Materials | |
| | -Cover Letter | 2 pages |
| | -Application for Pesticide Registration (EPA Form 8570-1) | 1 page |
| | -Transmittal Document | this page |
| | -Certification with Respect to Label Integrity | 1 page |
| | -Printed Labeling | 15 pages |
| | -Highlighted Label Indicating Changes | 15 pages |
| | -071654-00006.20110331.Virkon S.pdf | 1 CD |

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|---|---|
| 1. Company/Product Number 71654-6 | 2. EPA Product Manager Jacqueline Campbell-McFarlane | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Virkon(R) S | PM# 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company Attn: Susan Schaner Dupont Chemicals & Fluoroproducts, P. O. Box 80402 Wilmington, DE 19880-0402 <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |

Section - II

| | |
|--|--|
| <input checked="" type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amended labeling - Submitted in response to Accepted-With-Comments letter of July 15, 2010 and meeting of March 30, 2011. E-Label Master.

Section - III

| | | | |
|---|--|---|---|
| 1. Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. _____ No. per container _____ | If "Yes" Package wgt. 1.3 oz. No. per container 50 |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | 4. Size(s) Retail Container 10 lb., 4 lb, 1lb., 9 oz., | 5. Location of Label Directions <input checked="" type="checkbox"/> | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____ | | | |

Section - IV

| | | |
|--|------------------------------------|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name | Title | Telephone No. (Include Area Code) |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title Regulatory Coordinator | |
| 4. Typed Name Susan M. Schaner | 5. Date March 31, 2011 | |

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

| PROPOSED LABEL | | |
|--------------------|-----------------------|------------------------------------|
| EPA Registration # | Date Submitted to EPA | Electronic file name |
| 71654-6 | March 31, 2011 | 071654-00006.20110331.Virkon S.pdf |

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Susan M. Schaner
Signature

March 31, 2011

Date

Susan M. Schaner
Name (typed)

Regulatory Coordinator
Title

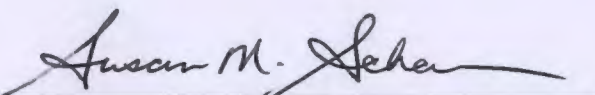
Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

| PROPOSED LABEL | | |
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| EPA Registration # | Date Submitted to EPA | Electronic file name |
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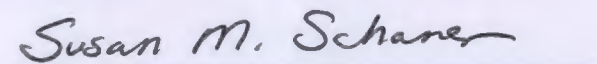
I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



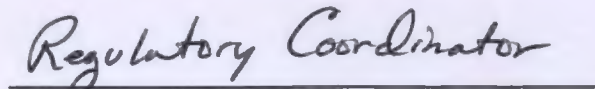
Signature

March 31, 2011

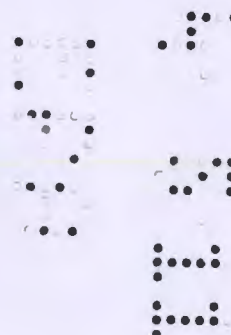
Date



Name (typed)



Title



8/6

| | | | | | | | |
|--|--|---|-----------------------------------|---|---|---|-----------------------------------|
| A | | Completed by Product Manager | | | | | |
| PRODUCT REVIEWER: Juan Negron | | | | | RMB II TEAM 34 | | |
| Description of Action: Notification | | | | | EPA File Symbol/Reg No.: 71654-6 | | |
| FQPA Action Code: 332 | | Non-FQPA Action Code: | | Fee for Service Action Code: | | | |
| Decision No. 437274 | | Submission No. 878644 | | Fee for Service Fee: \$ | | | |
| | | MONTH | | DAY | | YEAR | |
| APPLICATION DATE | | 7 | | 1 | | 2010 | |
| EPA PIN DATE | | 7 | | 6 | | 2010 | |
| REVIEWER ASSIGNED DATE | | 7 | | 16 | | 2010 | |
| DATE DUE TO PM | | | | | | 2010 | |
| DATE DUE OUT OF AGENCY | | | | | | 2010 | |
| Type of Data: | Product Chemistry <input type="checkbox"/> | Acute Toxicology <input type="checkbox"/> | Efficacy <input type="checkbox"/> | Environmental Fate <input type="checkbox"/> | Ecological Effects <input type="checkbox"/> | Chronic Toxicology <input type="checkbox"/> | Exposure <input type="checkbox"/> |
| Comments: Notification – Adding “Do not contaminate water, food, and feed by storage and disposal” to “Storage and Disposal” section | | | | | | | |
| ATTACHMENTS: <input checked="" type="checkbox"/> LABELING <input type="checkbox"/> CSFs <input type="checkbox"/> DATA <input type="checkbox"/> OTHER | | | | | | | |
| B | | For Arctic Slope Contract Only | | | | | |
| Contractor: Arctic Slope | | | | Contract No.: | | TOPO/Alt. TOPO: | |
| Draft Task: Signature _____ (Est. hrs) | | | | Final Task: Signature _____ (Total hrs) | | | |
| C | | | | Reviewers Comments: | | | |
| Response Code: 1155 | | | | Response Date: 8/5/2010 | | | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG - 5 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Susan M. Schaner
Regulatory Coordinator
DuPont Chemicals and Fluoroproducts
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: Product Name: Virkon® S
 EPA Registration No.: 71654-6
 Notification Date: July 1, 2010
 EPA Receipt Date: July 6, 2010

Dear Susan M. Schaner,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c) 9 and PR Notice 98-10.

Proposed Notification

- Updating the "Storage and Disposal" section.

General Comments

Based on a review of the submitted materials, your notification to add "Do not contaminate water, food, or feed by storage and disposal" statement is acceptable and apart of the records on file.

Should you have any questions or comments concerning this letter, please contact (Juan F. Negrón) at (703-308-8116).

Sincerely,

Jacqueline McFarlane
Jacqueline McFarlane
Product Manager (34)

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] [OPT]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against

•Viruses

Including Canine Parvovirus [OPT]

•Bacteria

•Fungi

NOTIFICATION
Date Reviewed: 8/5/10
Reviewed By: J. Ng

ACTIVE INGREDIENTS:

Potassium peroxymonosulfate..... 21.41%

Sodium Chloride..... 1.50%

OTHER INGREDIENTS..... 77.09%

TOTAL..... 100.00%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

See Inside Booklet for Additional Precautions [OPT]

See leaflet for additional directions for use [OPT]

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

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Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6

EPA Est. No. XXXXX-YY-ZZZ

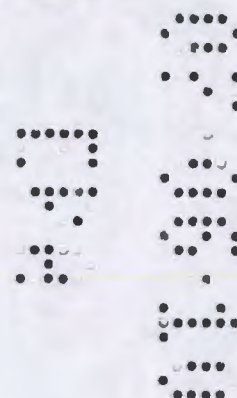
<Lot or batch #>

Front Panel Continued

| FIRST AID | |
|--|--|
| If in Eyes: | <ul style="list-style-type: none"> ● Hold eye open and rinse slowly and gently with water for 15-20 minutes. ● Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. ● Call a Poison Control Center or doctor for further treatment advice. |
| If on Skin or Clothing: | <ul style="list-style-type: none"> ● Take off contaminated clothing. ● Rinse skin immediately with plenty of water for 15-20 minutes. ● Call a Poison Control Center or doctor for further treatment advice. |
| If Swallowed: | <ul style="list-style-type: none"> ● Call a Poison Control Center or doctor immediately for treatment advice. ● Have person sip a glass of water if able to swallow. ● Do not induce vomiting unless told to do so by the poison control center or doctor ● Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. | |

Manufactured for:
E.I. DuPont de Nemours and Company
 PO Box 80023
 Wilmington, DE 19880-0023
 Questions? Call 1-800-441-7515
 Outside the US, contact: 1-302-774-1000

US Patent No. 4822512



EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**ANIMAL AND ZONOTIC PATHOGENS****BACTERIA**

Actinobacillus pleuropneumoniae
 Bacillus cereus
 Brucella abortus
 Campylobacter jejuni
 Clostridium perfringens
 Dermatophilus congolensis
 Escherichia coli
 Klebsiella pneumoniae
 Mycoplasma gallisepticum
 Pasteurella multocida
 Pseudomonas aeruginosa
 Salmonella enterica
 Salmonella typhimurium
 Shigella sonnei
 Staphylococcus aureus
 Staphylococcus epidermidis
 Streptococcus pyogenes
 Streptococcus suis

Not approved in California for use against the following bacteria:

Bordetella avium
 Bordetella bronchiseptica
 Fistulous withers (Poll Evil)
 Haemophilus somnus
 Helicobacter pylori
 Listeria monocytogenes
 Moraxella bovis (Pink Eye)
 Mycoplasma hyopneumonia
 Mycoplasma mycoides
 Pseudomonas mallei (Glanders)
 Pseudomonas vulgaris
 Streptococcus equi (Strangles)
 Taylorella equigenitalis
 Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
 Avian Laryngotracheitis Virus
 Bovine Adenovirus Type 4
 Canine Adenovirus (Canine Hepatitis)
 Canine Parvovirus
 Equine Herpes Virus (Type 1)
 Equine Herpes Virus (Type 3)
 Equine Influenza Virus (Type A)
 Feline Calicivirus
 Feline Panleukopenia Virus
 Feline Rhinotracheitis Virus
 Newcastle Disease Virus
 Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:

Adenovirus Pneumonia
 African Horse Sickness Virus
 African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
 Bovine Polyoma Virus
 Bovine Pseudocowpox Virus
 Bovine Viral Diarrhea Virus (no hard water)
 Calf Rotavirus (no hard water)
 Canine Coronavirus
 Canine Parainfluenza Virus
 Chicken Anemia Virus
 Coital Exanthema Virus
 Distemper Virus
 Duck Adenovirus (no hard water)
 Duck Enteritis Virus
 Egg Drop Syndrome Adenovirus
 Equine Infectious Anemia Virus (Swamp Fever)
 Equine Arteritis Virus (no hard water)

Not approved in California cont.

Equine Contagious Abortion Virus
 Equine Papillomatosis Virus
 Equine Influenza Virus (The Cough)
 Feline Herpes Virus
 Feline Infectious Peritonitis Virus
 Feline Parvovirus
 Foot and Mouth Disease Virus
 Hog Cholera Virus
 Infectious Bronchitis Virus
 Infectious Bursal Disease Virus
 Infectious Canine Hepatitis Virus
 Infectious Pancreatic Necrosis Virus
 Infectious Salmon Anaemia Virus
 Infective Bovine Rhinotracheitis Virus (no hard water)
 Leptospira Canicola Virus
 Maedi- Visna Virus
 Marek's Disease Virus
 Mouse Parvovirus
 PCV2 Virus (PMWS)
 Porcine Parvovirus
 Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
 Pseudorabies Virus (Aujeszky's Disease) (no hard water)
 Rotaviral Diarrhea Virus
 Snakehead rhabdovirus
 Swine Influenza Virus
 Swine Vesicular Disease Virus
 Transmissible Gastroenteritis Virus (TGE) (no hard water)
 Turkey Herpes Virus (no hard water)
 Turkey Rhinotracheitis Virus
 Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagrophytes (2%)

Not approved in California for use against the following fungi:

Aspergillus fumigatus

Fusarium moniliforme

Microsporum canis

Trichophyton spp. (Ringworm)

Trichophyton spp. (Mud Fever)

PLANT PATHOGENS

Not approved in California for use against plant pathogens:

Alternaria solani

Botrytis cinera

Colletotrichum coccodes

Didymella bryoniae

Fusarium oxysporum

Fusarium solani

Penicillium oxalicum

Phomopsis sclerotioides

Pyrenochaeta lycoopersici

Pythium aphanidermatum

Rhizoctonia solani

Sclerotinia sclerotiorum

Thielaviopsis basicola

Verticillium dahliae

Xanthomonas axonopodis

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use-diluted solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts – *Not Approved for this use in California*), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., “no hard water,” “no soil load,” and “use 2% solution.”

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Virkon® S [OPT] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus. [OPT]

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu). [OPT]

Kills Pandemic 2009 H1N1 influenza A virus. [OPT]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT.]

Powder

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|---------------------|
| 1 Quart | 0.15 ounces* | 0.3 ounces | 0.7 ounces |
| 1 Gallon | 0.65 ounces* | 1.3 ounces | 2.7 ounces |
| 10 Gallons | 6.7 ounces* | 13.4 ounces | 26.7 ounces |
| 50 Gallons | 33.4 ounces* | 66.8 ounces | 133.5 ounces |

Measuring cup provided.

Tablet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|--------------------|
| 1 Pint | | 1 tablet | 2 tablets |
| 1 Quart | 1 tablet* | 2 tablets | 4 tablets |
| 1 Gallon | 4 tablets* | 8 tablets | 16 tablets |

Sachet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|--------------------|
| 1 gallon | - | 1 Sachet | 2 Sachets |
| 2 Gallons | 1 Sachet | 2 Sachets | 4 Sachets |

* The 0.5% solution currently is not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Mycoplasma gallisepticum*. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts – *Not Approved for this use in California*) *Aspergillus flavus*, Fungi of *Aspergillus fumigatus* and Bacteria of *Bordetella avium*, *Helicobacter pylori*.

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

CONTROLS: Bacteria of *Actinobacillus Pleuropneumoniae* and *Clostridium perfringens*. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of *Fusarium moniliforme*, Foot and Mouth Disease and Bacteria of *Treponema hyodysenteriae*.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of *Fusarium moniliforme*, Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of *Clostridial Diarrhea*, *Fistulous Withers* (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders); Fungi of *Dermatophytosis* (Ringworm) and *Dermatophylosis* (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4. *Not approved in California for use against the following organisms:* Bacteria of *Moraxella bovis* and Fungi of *Fusarium moniliforme*. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of *Haemophilus somnus*.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. *Not approved in California for use against the following organisms:* Viruses of Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes; Fungi of *Microsporum canis*.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

- 1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.
- 2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers: *Not approved use in California:* Treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

| Disease Organism | Dilution Rate | Oz./Gal. |
|-------------------|---------------|----------|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

[For spray bottle with in-use solution]: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. [Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.] Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.



DuPont Chemicals and Fluoroproducts

DuPont Chemicals and Fluoroproducts
P. O. Box 80402
Wilmington, DE 19880-0402

July 1, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Jacqueline McFarlane
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

SUBJECT: Virkon® S, EPA Registration Number 71654-6
Notification of master label upgrade per PR Notice 98-10

Dear Ms. McFarlane,

Please consider this letter and its enclosures as a notification to upgrade the master label for the above referenced product. On page 14 of the enclosed master label, we are adding the following:

- "Do not contaminate water, food, and feed by storage and disposal."

Enclosed please find the following documents supporting this notification:

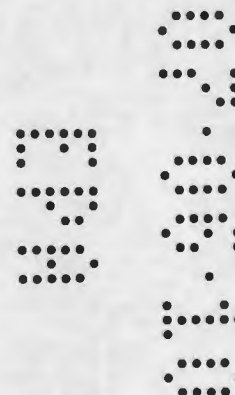
- Completed application for Pesticide Registration (EPA form 8570-1) – dated July 1, 2010
- Two copies of the master label (one with corrections highlighted) (14 pages ea)
- One CD with Master e-label, 071654.00006.20100701.MasterVirkonS.Upgrade.pdf

Should you have any questions, please feel free to call me at (302)695-2328 or email susan.m.schaner@usa.dupont.com.

Sincerely,

Susan M. Schaner
Regulatory Coordinator
DuPont Chemicals and Fluoroproducts

Enclosures





EPA

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
☐ Amendment
☒ Other: Notification

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|---|--|
| 1. Company/Product Number 71654-6 | 2. EPA Product Manager Jacqueline McFarlane (acting) | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Virkon S | PM# Team 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company DuPont Chemical Solutions Enterprise P.O. Box 80402 (E403-3224D) Wilmington, DE 19880-0402 Attn: Susan M. Schaner | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |
| <input type="checkbox"/> Check if this is a new address | | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

"Notification of master label upgrade per PR Notice 98-10"

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formulas for the product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

| | | | | | |
|---|---|--|--------------------------|---|--|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | | <input type="checkbox"/> Metal | |
| | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt. | No. per container | <input type="checkbox"/> Plastic |
| *Certification must be submitted | | | | | <input type="checkbox"/> Glass |
| | | | | | <input type="checkbox"/> Paper |
| | | | | | <input type="checkbox"/> Other (Specify) |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other | | | |

Section - IV

| | | |
|--|---|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application). | | |
| Name Susan M. Schaner | Title Regulatory Coordinator | Telephone No. (Include Area Code) (302) 695-2328 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature <i>Susan M. Schaner</i> | 3. Title Regulatory Coordinator | |
| 4. Typed Name Susan M. Schaner | 5. Date 1-Jul-2010 | |

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

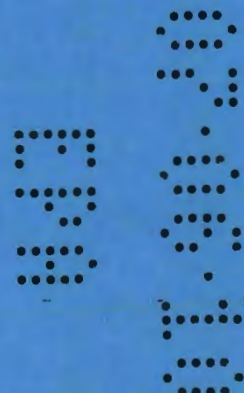
then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

| | | |
|------|---------------|----------|
| AD | Willie Abney | 308-1689 |
| | Rena Whitaker | 308-7003 |
| | Tracy Lantz | 308-6415 |
| BPPD | | |
| RD | Tom Harris | 308-9423 |



Material to be added to an e-Jacket/Jacket

Reg. No. 71654-6

Description: _____

1. ☐ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top = newest)
 - ☐ File Location: (PDF page number, i.e., "before page 45")
- _____
- _____

2. ☒ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
- ☒ Notification
- ☐ New CSF
- ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Stacy Grigby

Phone: _____ Division: AD

Date: 5/21/2010

Created August 14, 2008



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

E COPY

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAY 2 1 2010

Susan M. Schaner
Du Pont Chemicals and Fluoroproducts
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon® S**
EPA Registration No.: 71654-6
Application Date: April 12, 2010
Receipt Date: April 21, 2010

Dear Ms. Schaner:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c) 9.

Proposed Notification:

- Updating Storage and Disposal Update PR Notice 2007-4
- Update Directions for Use

General Comment:

Based on a review of the material submitted, the following comment applies:

A copy of the accepted notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)



DuPont Chemicals and Fluoroproducts

DuPont Chemicals and Fluoroproducts
P. O. Box 80402
Wilmington, DE 19880-0402

April 13, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
Jacqueline McFarlane (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: Virkon® S, EPA Registration #: 71654-6
Notification to correct the master label on PPLS Website

Dear Ms. McFarlane,

It has come to our attention that the label posted on the PPLS website for the above referenced product related to the PR 2007-4 notification is incorrect. The posted label is from a submission that received pin-punch May 20, 2008. The May 2008 submission did not contain upgraded container disposal language and has directions for use which have not been accepted to date.

Please consider this letter and its attachments as a notification to correct the master label for the above referenced product. The attached label also incorporates the revision required by your July 1, 2009 Accepted with Comments letter.

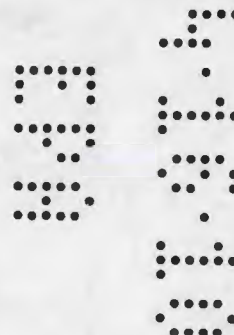
Please refer to the attached:

- Completed application for Pesticide Registration (EPA form 8570-1) – dated April 9, 2010
- Two copies of the master label (one with corrections highlighted) (14 pages ea)
- One copy of label posted on PPLS Website – dated July 1, 2009 (16 pages)
- One CD with Master e-label, 071654.00006.20100409.MasterVirkonS.Corrected.pdf

Should you have any questions, please feel free to call me at (302)695-2328 or email susan.m.schaner@usa.dupont.com.

Sincerely,

Susan M. Schaner
Regulatory Coordinator
DuPont Chemicals and Fluoroproducts



**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
☐ Amendment
☒ Other: Notification

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|---|
| 1. Company/Product Number 71654-6 | 2. EPA Product Manager Jacqueline McFarlane (acting) | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Virkon S | PM# Team 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company DuPont Chemical Solutions Enterprise P.O. Box 80402 (E403-3224D) Wilmington, DE 19880-0402 Attn: Susan M. Schaner | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |

☐ Check if this is a new address

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

This notification is to correct the master label posted on the PPLS website.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formulas for the product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

| | | | |
|---|---|---|--|
| 1. Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container | 2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) |
| *Certification must be submitted | | | |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | 4. Size(s) Retail Container | 5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | |

Section - IV

| | | | |
|--|---|--|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) | | | |
| Name Susan M. Schaner | Title Regulatory Coordinator | Telephone No. (Include Area Code) (302) 695-2328 | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title Regulatory Coordinator | | |
| 4. Typed Name Susan M. Schaner | 5. Date 09-Apr-2010 | | |

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] [OPT]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against

•Viruses

Including Canine Parvovirus [OPT]

•Bacteria

•Fungi

ACTIVE INGREDIENTS:

| | |
|----------------------------------|---------------|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | <u>77.09%</u> |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

See Inside Booklet for Additional Precautions [OPT]

See leaflet for additional directions for use [OPT]

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

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Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6

EPA Est. No. XXXXX-YY-ZZZ

<Lot or batch #>

Front Panel Continued

| FIRST AID | |
|--|--|
| If in Eyes: | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice. |
| If on Skin or Clothing: | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice. |
| If Swallowed: | <ul style="list-style-type: none"> • Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. | |

Manufactured for:
E.I. DuPont de Nemours and Company
 PO Box 80023
 Wilmington, DE 19880-0023
 Questions? Call 1-800-441-7515
 Outside the US, contact: 1-302-774-1000

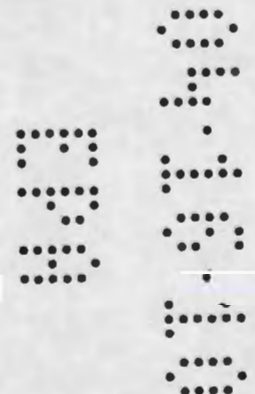
US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**ANIMAL AND ZONOTIC PATHOGENS****BACTERIA**

Actinobacillus pleuropneumoniae
 Bacillus cereus
 Brucella abortus
 Campylobacter jejuni
 Clostridium perfringens
 Dermatophilus congolensis
 Escherichia coli
 Klebsiella pneumoniae
 Mycoplasma gallisepticum
 Pasteurella multocida
 Pseudomonas aeruginosa
 Salmonella enterica
 Salmonella typhimurium
 Shigella sonnei
 Staphylococcus aureus
 Staphylococcus epidermidis
 Streptococcus pyogenes
 Streptococcus suis

Not approved in California for use against the following bacteria:

Bordetella avium
 Bordetella bronchiseptica
 Fistulous withers (Poll Evil)
 Haemophilus somnus
 Helicobacter pylori
 Listeria monocytogenes
 Moraxella bovis (Pink Eye)
 Mycoplasma hyopneumonia
 Mycoplasma mycoides
 Pseudomonas mallei (Glanders)
 Pseudomonas vulgaris
 Streptococcus equi (Strangles)
 Taylorella equigenitalis
 Treponema hyodysenteriae



VIRUSES

Avian Influenza Virus
 Avian Laryngotracheitis Virus
 Bovine Adenovirus Type 4
 Canine Adenovirus (Canine Hepatitis)
 Canine Parvovirus
 Equine Herpes Virus (Type 1)
 Equine Herpes Virus (Type 3)
 Equine Influenza Virus (Type A)
 Feline Calicivirus
 Feline Panleukopenia Virus
 Feline Rhinotracheitis Virus
 Newcastle Disease Virus
 Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:

Adenovirus Pneumonia
 African Horse Sickness Virus
 African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
 Bovine Polyoma Virus
 Bovine Pseudocowpox Virus
 Bovine Viral Diarrhea Virus (no hard water)
 Calf Rotavirus (no hard water)
 Canine Coronavirus
 Canine Parainfluenza Virus
 Chicken Anemia Virus
 Coital Exanthema Virus
 Distemper Virus
 Duck Adenovirus (no hard water)
 Duck Enteritis Virus
 Egg Drop Syndrome Adenovirus
 Equine Infectious Anemia Virus (Swamp Fever)
 Equine Arteritis Virus (no hard water)

Not approved in California cont.

Equine Contagious Abortion Virus
 Equine Papillomatosis Virus
 Equine Influenza Virus (The Cough)
 Feline Herpes Virus
 Feline Infectious Peritonitis Virus
 Feline Parvovirus
 Foot and Mouth Disease Virus
 Hog Cholera Virus
 Infectious Bronchitis Virus
 Infectious Bursal Disease Virus
 Infectious Canine Hepatitis Virus
 Infectious Pancreatic Necrosis Virus
 Infectious Salmon Anaemia Virus
 Infective Bovine Rhinotracheitis Virus (no hard water)
 Leptospira Canicola Virus
 Maedi-Visna Virus
 Marek's Disease Virus
 Mouse Parvovirus
 PCV2 Virus (PMWS)
 Porcine Parvovirus
 Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
 Pseudorabies Virus (Aujeszky's Disease) (no hard water)
 Rotaviral Diarrhea Virus
 Snakehead rhabdovirus
 Swine Influenza Virus
 Swine Vesicular Disease Virus
 Transmissible Gastroenteritis Virus (TGE) (no hard water)
 Turkey Herpes Virus (no hard water)
 Turkey Rhinotracheitis Virus
 Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagrophytes (2%)

Not approved in California for use against the following fungi:

Aspergillus fumigatus

Fusarium moniliforme

Microsporum canis

Trichophyton spp. (Ringworm)

Trichophyton spp. (Mud Fever)

PLANT PATHOGENS

Not approved in California for use against plant pathogens:

Alternaria solani

Botrytis cinera

Colletotrichum coccodes

Didymella bryoniae

Fusarium oxysporum

Fusarium solani

Penicillium oxalicum

Phomopsis sclerotioides

Pyrenochaeta lycoopersici

Pythium aphanidermatum

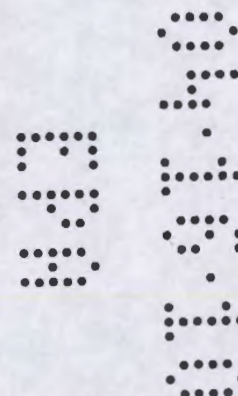
Rhizoctonia solani

Sclerotinia sclerotiorum

Thielaviopsis basicola

Verticillium dahliae

Xanthomonas axonopodis



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use-diluted solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts – *Not Approved for this use in California*), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., “no hard water,” “no soil load,” and “use 2% solution.”

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Virkon® S [OPT] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus. [OPT]

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu). [OPT]

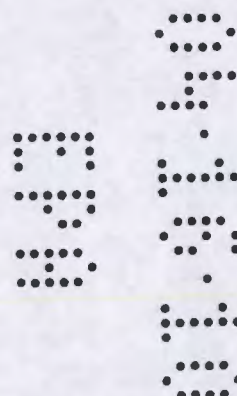
Kills Pandemic 2009 H1N1 influenza A virus. [OPT]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.



Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT.]

Powder

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|---------------------|
| 1 Quart | 0.15 ounces* | 0.3 ounces | 0.7 ounces |
| 1 Gallon | 0.65 ounces* | 1.3 ounces | 2.7 ounces |
| 10 Gallons | 6.7 ounces* | 13.4 ounces | 26.7 ounces |
| 50 Gallons | 33.4 ounces* | 66.8 ounces | 133.5 ounces |

Measuring cup provided.

Tablet

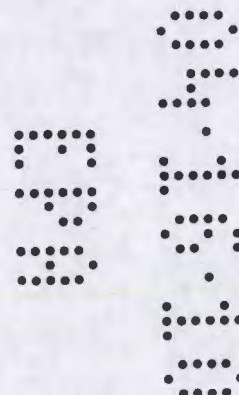
| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|--------------------|
| 1 Pint | | 1 tablet | 2 tablets |
| 1 Quart | 1 tablet* | 2 tablets | 4 tablets |
| 1 Gallon | 4 tablets* | 8 tablets | 16 tablets |

Sachet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|--------------------|
| 1 gallon | - | 1 Sachet | 2 Sachets |
| 2 Gallons | 1 Sachet | 2 Sachets | 4 Sachets |

* The 0.5% solution currently is not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]



POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Mycoplasma gallisepticum*. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts – *Not Approved for this use in California*) *Aspergillus flavus*, Fungi of *Aspergillus fumigatus* and Bacteria of *Bordetella avium*, *Helicobacter pylori*.

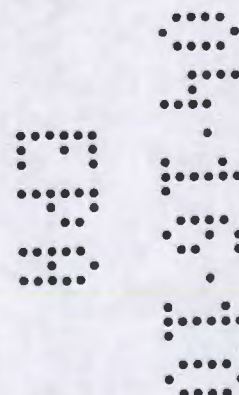
HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.



SWINE PRODUCTION

CONTROLS: Bacteria of *Actinobacillus Pleuropneumoniae* and *Clostridium perfringens*. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of *Fusarium moniliforme*, Foot and Mouth Disease and Bacteria of *Treponema hyodysenteriae*.

Follow General Instructions to remove swine and pre-clean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of *Fusarium moniliforme*, Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of *Clostridial Diarrhea*, *Fistulous Withers* (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders); Fungi of *Dermatophytosis* (Ringworm) and *Dermatophylosis* (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4. *Not approved in California for use against the following organisms:* Bacteria of *Moraxella bovis* and Fungi of *Fusarium moniliforme*. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of *Haemophilus somnus*.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. *Not approved in California for use against the following organisms:* Viruses of Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes; Fungi of *Microsporum canis*.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.

2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers: *Not approved use in California:* Treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

| Disease Organism | Dilution Rate | Oz./Gal. |
|-------------------|---------------|----------|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

[For sprav bottle with in-use solution]: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. [Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.] Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

[For spray bottle with in-use solution: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.

[Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.] Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 2 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thomas C. McEntee
Product Registration Manager
E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL402/3224A)
P.O. Box 80402
Wilmington, DE 19880-0402

FILE COPY

Subject: Notification Application per PR Notice 95-2
Virkon® S
EPA Registration Number: 71654-6
Application Date: November 11, 2009
Receipt Date: November 12, 2009

Dear Mr. McEntee:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 95-2.

Proposed Notification:

Addition of Influenza A virus (H1N1) label claim

General Comment:

Based on a review of the material submitted, the following comment applies:

The notification is acceptable.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at garvie.heather@epa.gov.

Sincerely,

ShaRon Carlisle
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] {OPT}

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT]
•Bacteria
•Fungi

NOTIFICATION
Date Reviewed: 12/2/09
Reviewed By: [Signature]

ACTIVE INGREDIENTS:

| | |
|----------------------------------|----------------|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

See Inside Booklet for Additional Precautions

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

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Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6

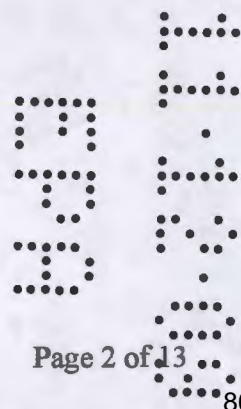
EPA Est. No. XXXXX-YY-ZZZ

Front Panel Continued

| FIRST AID | |
|--|---|
| If in Eyes: | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present after 5 minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for further treatment advice. |
| If on Skin or Clothing: | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for further treatment advice. |
| If Swallowed: | <ul style="list-style-type: none">• Call Poison Control Center or doctor immediately for treatment advice.• Have Person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor• Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| For 24-hour emergency information on this product, call 1-800-3637 (US & Canada) or 1-302-774-1100 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. | |

Manufactured for:
E.I. DuPont de Nemours and Company
PO Box 80023
Wilmington, DE 19880-0023
Questions? Call 1 800 441-7515

US Patent No. 4822512



EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:

ANIMAL AND ZOO NOTIC PATHOGENS

BACTERIA

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

*Not approved in California for use against
the following bacteria:*

Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycoplasma hyopneumonia
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
Avian Laryngotracheitis Virus
Bovine Adenovirus Type 4
Canine Adenovirus (Canine Hepatitis)
Canine Parvovirus
Equine Herpes Virus (Type 1)
Herpes Virus Equine (Type 3)
Equine Influenza Virus (Type A)
Feline Calicivirus
Feline Panleukopenia Virus
Feline Rhinotracheitis Virus
Newcastle Disease Virus
Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:

Adenovirus Pneumonia
African Horse Sickness Virus
African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (no hard water)
Calf Rotavirus (no hard water)
Canine Coronavirus
Canine Parainfluenza Virus
Chicken Anemia Virus
Coital Exanthema Virus
Distemper Virus
Duck Adenovirus (no hard water)
Duck Enteritis Virus
Egg Drop Syndrome Adenovirus
Equine Infectious Anemia Virus (Swamp Fever)
Equine Arteritis Virus (no hard water)

Not approved in California cont.

Hog Cholera Virus
Equine Contagious Abortion Virus
Equine Papillomatosis Virus
Equine Influenza Virus (The Cough)
Feline Herpes Virus
Feline Infectious Peritonitis Virus
Feline Parvovirus
Foot and Mouth Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Disease Virus
Infectious Canine Hepatitis Virus
Infectious Pancreatic Necrosis Virus
Infectious Salmon Anaemia Virus
Infective Bovine Rhinotracheitis Virus (no hard water)
Leptospira Canicola Virus
Maedi-Visna Virus
Marek's Disease Virus
Mouse Parvovirus
PCV2 Virus (PMWS)
Porcine Parvovirus
Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Pseudorabies Virus (Aujeszky's Disease) (no hard water)
Rotaviral Diarrhea Virus
Snakehead rhabdovirus
Swine Influenza Virus
Swine Vesicular Disease Virus
Transmissible Gastroenteritis Virus (TGE) (no hard water)
Turkey Herpes Virus (no hard water)
Turkey Rhinotracheitis Virus
Vesicular Stomatitis Virus

FUNGI

Trichophyton mentagrophytes (2%)

Not approved in California for use against the following fungi:

Aspergillus fumigatus

Fusarium moniliforme

Microsporum canis

Trichophyton spp. (Ringworm)

Trichophyton spp. (Mud Fever)

PLANT PATHOGENS

Not approved in California for use against plant pathogens:

Alemaria solani

Botrytis cinera

Colletotrichum coccodes

Didymella bryoniae

Fusarium oxysporum

Fusarium solani

Penicillium oxalicum

Phomopsis sclerotioides

Pyrenochaeta lycoopersici

Pythium aphanidermatum

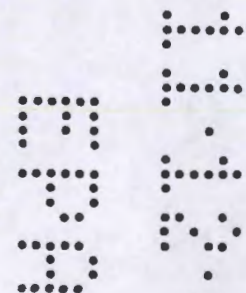
Rhizoctonia solani

Sclerotinia sclerotiorum

Thielaviopsis basicola

Verticillium dahliae

Xanthomonas axonopodis



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

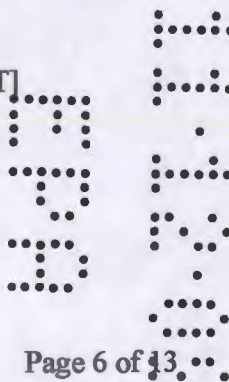
Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Virkon® S [OPT] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).[OPT]

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus. [OPT]

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).[OPT]

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu). [OPT]

Kills Pandemic 2009 H1N1 influenza A virus. [OPT]



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

Powder

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|--------------|
| 1 Quart | 0.15 ounces* | 0.3 ounces | 0.7 ounces |
| 1 Gallon | 0.65 ounces* | 1.3 ounces | 2.7 ounces |
| 10 Gallons | 6.7 ounces* | 13.4 ounces | 26.7 ounces |
| 50 Gallons | 33.4 ounces* | 66.8 ounces | 133.5 ounces |

Measuring cup provided.

Tablet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|-------------|
| 1 Pint | | 1 tablet | 2 tablets |
| 1 Quart | 1 tablet* | 2 tablets | 4 tablets |
| 1 Gallon | 4 tablets* | 8 tablets | 16 tablets |

* The 0.5% solution currently is not approved for use in California.

Sachet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|-------------------|----------------|-------------|-------------|
| 1 gallon | - | 1 Sachet | 2 Sachets |
| 2 Gallons | 1 Sachet | 2 Sachets | 4 Sachets |

* The 0.5% solution is currently not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Mycoplasma gallisepticum*. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) *Aspergillus flavus*, Fungi of *Aspergillus fumigatus* and Bacteria of *Bordetella avium*, *Helicobacter pylori*.

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

CONTROLS: Bacteria of *Actinobacillus Pleuropneumoniae* and *Clostridium perfringens*; *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of *Fusarium moniliforme* Foot and Mouth Disease and Bacteria of *Treponema hyodysenteriae*.

Follow General Instructions to remove swine and preclean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of *Fusarium moniliforme*. Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of Clostridial Diarrhea, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders); Fungi of Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; *Not approved in California for use against the following organisms:* Bacteria of *Moraxella bovis* and Fungi of *Fusarium moniliforme*. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of *Haemophilus somnus*.

Follow General Instructions to remove livestock and pre-clean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. *Not approved in California for use against the following organisms:* Viruses of Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes; Fungi of *Microsporum canis*.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

- 1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.
- 2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control.

For clean non-porous surfaces

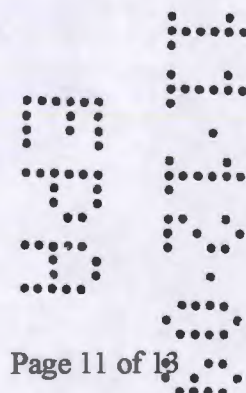
Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California*: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California*: Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.



AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and *Mycoplasma mycoides* (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

| Disease Organism | Dilution rate | Oz./Gal. |
|-------------------|---------------|----------|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE Store out of reach of children.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] [OPT]

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT]
•Bacteria
•Fungi

ACTIVE INGREDIENTS:

| | |
|----------------------------------|---------|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | 77.09% |
| TOTAL..... | 100.00% |

NOTIFICATION
Date Reviewed: 5/13/10
Reviewed By: S. B. [signature]

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

See Inside Booklet for Additional Precautions [OPT]

See leaflet for additional directions for use [OPT]

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

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EPA Reg. No. 71654-6

EPA Est. No. XXXXX-YY-ZZZ

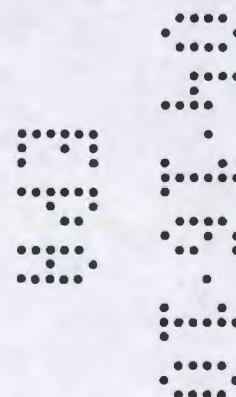
<Lot or batch #>

Front Panel Continued

| FIRST AID | |
|--|--|
| If in Eyes: | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice. |
| If on Skin or Clothing: | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice. |
| If Swallowed: | <ul style="list-style-type: none"> • Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| For 24-hour emergency information on this product, call 1-800-441-3637 (US & Canada) or 1-302-774-1139 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. | |

Manufactured for:
E.I. DuPont de Nemours and Company
 PO Box 80023
 Wilmington, DE 19880-0023
 Questions? Call 1-800-441-7515
 Outside the US, contact: 1-302-774-1000

US Patent No. 4822512

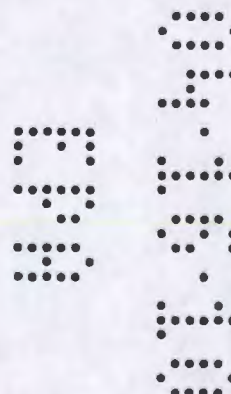


EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**ANIMAL AND ZOONOTIC PATHOGENS****BACTERIA**

Actinobacillus pleuropneumoniae
 Bacillus cereus
 Brucella abortus
 Campylobacter jejuni
 Clostridium perfringens
 Dermatophilus congolensis
 Escherichia coli
 Klebsiella pneumoniae
 Mycoplasma gallisepticum
 Pasteurella multocida
 Pseudomonas aeruginosa
 Salmonella **enterica**
 Salmonella typhimurium
 Shigella sonnei
 Staphylococcus aureus
 Staphylococcus epidermidis
 Streptococcus pyogenes
 Streptococcus suis

Not approved in California for use against the following bacteria:

Bordetella avium
 Bordetella bronchiseptica
 Fistulous withers (Poll Evil)
 Haemophilus somnus
 Helicobacter pylori
 Listeria monocytogenes
 Moraxella bovis (Pink Eye)
 Mycoplasma hyopneumonia
 Mycoplasma mycoides
 Pseudomonas mallei (Glanders)
 Pseudomonas vulgaris
 Streptococcus equi (Strangles)
 Taylorella equigenitalis
 Treponema hyodysenteriae



VIRUSES

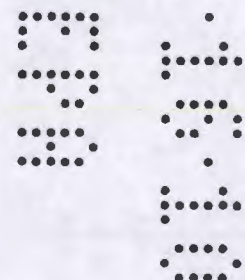
Avian Influenza Virus
 Avian Laryngotracheitis Virus
 Bovine Adenovirus Type 4
 Canine Adenovirus (Canine Hepatitis)
 Canine Parvovirus
 Equine Herpes Virus (Type 1)
 Equine Herpes Virus (Type 3)
 Equine Influenza Virus (Type A)
 Feline Calicivirus
 Feline Panleukopenia Virus
 Feline Rhinotracheitis Virus
 Newcastle Disease Virus
 Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:

Adenovirus Pneumonia
 African Horse Sickness Virus
 African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
 Bovine Polyoma Virus
 Bovine Pseudocowpox Virus
 Bovine Viral Diarrhea Virus (no hard water)
 Calf Rotavirus (no hard water)
 Canine Coronavirus
 Canine Parainfluenza Virus
 Chicken Anemia Virus
 Coital Exanthema Virus
 Distemper Virus
 Duck Adenovirus (no hard water)
 Duck Enteritis Virus
 Egg Drop Syndrome Adenovirus
 Equine Infectious Anemia Virus (Swamp Fever)
 Equine Arteritis Virus (no hard water)

Not approved in California cont.

Equine Contagious Abortion Virus
 Equine Papillomatosis Virus
 Equine Influenza Virus (The Cough)
 Feline Herpes Virus
 Feline Infectious Peritonitis Virus
 Feline Parvovirus
 Foot and Mouth Disease Virus
 Hog Cholera Virus
 Infectious Bronchitis Virus
 Infectious Bursal Disease Virus
 Infectious Canine Hepatitis Virus
 Infectious Pancreatic Necrosis Virus
 Infectious Salmon Anaemia Virus
 Infective Bovine Rhinotracheitis Virus (no hard water)
 Leptospira Canicola Virus
 Maedi- Visna Virus
 Marek's Disease Virus
 Mouse Parvovirus
 PCV2 Virus (PMWS)
 Porcine Parvovirus
 Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
 Pseudorabies Virus (Aujeszky's Disease) (no hard water)
 Rotaviral Diarrhea Virus
 Snakehead rhabdovirus
 Swine Influenza Virus
 Swine Vesicular Disease Virus
 Transmissible Gastroenteritis Virus (TGE) (no hard water)
 Turkey Herpes Virus (no hard water)
 Turkey Rhinotracheitis Virus
 Vesicular Stomatitis Virus



FUNGI

Trichophyton mentagrophytes (2%)

Not approved in California for use against the following fungi:

Aspergillus fumigatus

Fusarium moniliforme

Microsporum canis

Trichophyton spp. (Ringworm)

Trichophyton spp. (Mud Fever)

PLANT PATHOGENS

Not approved in California for use against plant pathogens:

Alternaria solani

Botrytis cinera

Colletotrichum coccodes

Didymella bryoniae

Fusarium oxysporum

Fusarium solani

Penicillium oxalicum

Phomopsis sclerotioides

Pyrenochaeta lycoopersici

Pythium aphanidermatum

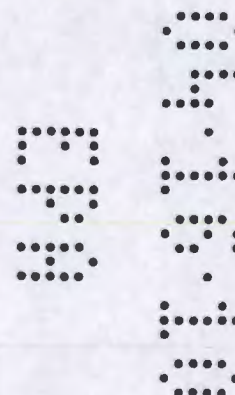
Rhizoctonia solani

Sclerotinia sclerotiorum

Thielaviopsis basicola

Verticillium dahliae

Xanthomonas axonopodis



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use-diluted solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts – *Not Approved for this use in California*), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., “no hard water,” “no soil load,” and “use 2% solution.”

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Virkon® S [OPT] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus. [OPT]

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). [OPT]

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu). [OPT]

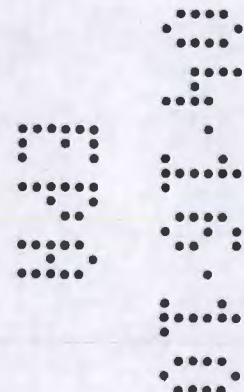
Kills Pandemic 2009 H1N1 influenza A virus. [OPT]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.



Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT.]

Powder

| Quantity of Water | 0.5% Solution * | 1% Solution | 2% Solution |
|--------------------------|------------------------|--------------------|---------------------|
| 1 Quart | 0.15 ounces* | 0.3 ounces | 0.7 ounces |
| 1 Gallon | 0.65 ounces* | 1.3 ounces | 2.7 ounces |
| 10 Gallons | 6.7 ounces* | 13.4 ounces | 26.7 ounces |
| 50 Gallons | 33.4 ounces* | 66.8 ounces | 133.5 ounces |

Measuring cup provided.

Tablet

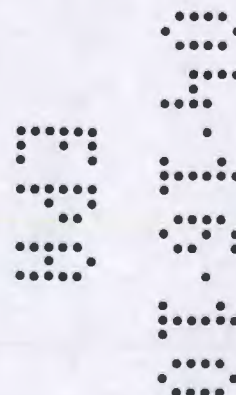
| Quantity of Water | 0.5% Solution * | 1% Solution | 2% Solution |
|--------------------------|------------------------|--------------------|--------------------|
| 1 Pint | | 1 tablet | 2 tablets |
| 1 Quart | 1 tablet* | 2 tablets | 4 tablets |
| 1 Gallon | 4 tablets* | 8 tablets | 16 tablets |

Sachet

| Quantity of Water | 0.5% Solution * | 1% Solution | 2% Solution |
|--------------------------|------------------------|--------------------|--------------------|
| 1 gallon | - | 1 Sachet | 2 Sachets |
| 2 Gallons | 1 Sachet | 2 Sachets | 4 Sachets |

* The 0.5% solution currently is not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]



POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Mycoplasma gallisepticum*. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts – *Not Approved for this use in California*) *Aspergillus flavus*, Fungi of *Aspergillus fumigatus* and Bacteria of *Bordetella avium*, *Helicobacter pylori*.

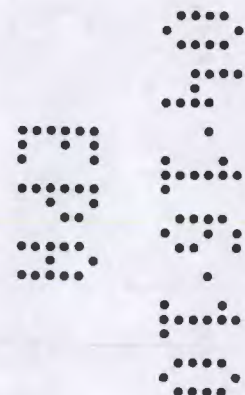
HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and preclean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.



SWINE PRODUCTION

CONTROLS: Bacteria of *Actinobacillus Pleuropneumoniae* and *Clostridium perfringens*. *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of *Fusarium moniliforme*, Foot and Mouth Disease and Bacteria of *Treponema hyodysenteriae*.

Follow General Instructions to remove swine and pre-clean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of *Fusarium moniliforme*, Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of *Clostridial Diarrhea*, *Fistulous Withers* (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders); Fungi of *Dermatophytosis* (Ringworm) and *Dermatophylosis* (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4. *Not approved in California for use against the following organisms:* Bacteria of *Moraxella bovis* and Fungi of *Fusarium moniliforme*. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of *Haemophilus somnus*.

Follow General Instructions to remove livestock and pre-clean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. *Not approved in California for use against the following organisms:* Viruses of Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes; Fungi of *Microsporum canis*.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

- 1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.
- 2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*

- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers: *Not approved use in California:* Treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California:* Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

| Disease Organism | Dilution Rate | Oz./Gal. |
|-------------------|---------------|----------|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges or other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE:

For pails, [jugs], [bottles]: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in a cool dry place. Keep out of reach of children. [Retain dessicant canister with product during storage.] Do not mix this product with other chemicals.

[For spray bottle with in-use solution: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. [Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment.] Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Material to be added to an e-Jacket/Jacket

Reg. No. 71654-6

1. ☐ Placement within the e-Jacket/jacket:

☐ Default: (chronological, top/newest)

☐ Description: (PDF page number, i.e., "before page 45")

2. ☒ Send to Data Extraction contractors this material:

☐ Newly stamped accepted label

☒ Notification

☐ New CSF

☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Heather Harris

Phone: _____ Division: AD

Date: 12/2/09

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

| | | | | | | | | |
|--|------------------------------|-------------------------------|--------------|------------------------------|--------------------------|--|------------------------|--|
| A | Completed by Product Manager | | | | | | | |
| PRODUCT REVIEWER: HEATHER GARVIE | | | | | | RMB <u>II</u> TEAM <u>34</u> | | |
| Description of Action: NOTIFICATION | | | | | | EPA File Symbol/Reg No. 71654-6 | | |
| Decision No. <u>423482</u> | | Submission No. <u>862 768</u> | | Fee for Service Action Code: | | | | |
| FQPA Action Code: 332 | | Non-FQPA Action Code: | | PRIA FEE AMOUNT: \$ | | | | |
| | MONTH | DAY | YEAR | | | | | |
| APPLICATION DATE | 11 | 11 | 2009 | | | | | |
| EPA PIN DATE | 11 | 12 | 2009 | | | | | |
| DATE PM RECEIVED FROM FRONT END | 11 | 17 | 2009 | | | | | |
| Date sent to Reviewer | 11 | 18 | 2009 | | | | | |
| DATE SENT TO SCIENCE <small>[VIVIAN COMPLETES]</small> | | | 2009 | | | | | |
| DATE RECEIVED FROM SCIENCE | | | | | | | | |
| NEGOTIATED DUE DATE | | | | DATE DUE OUT OF AGENCY | | 12-12-09 | | |
| Type of Data: | PSB Product Chemistry | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure/Residue | |
| COMMENTS: ADDING INFLUENZA A H1N1 CLAIM | | | | | | | | |
| | | | | | | | | |
| ATTACHMENTS: <input checked="" type="checkbox"/> -LABELING <input type="checkbox"/> -CSF(S) <input type="checkbox"/> -DATA <input type="checkbox"/> -OTHERS | | | | | | | | |
| DATE FEE PAID: | | | | RESPONSE CODE: <u>1155</u> | | RESPONSE DATE: <u>12/2/09</u> ¹¹³ | | |



Re: 71654-6 - Notification to add H1N1

Thomas C McEntee to: Heather Garvie

12/01/2009 11:51 AM

unacceptable

46166018 Parsons, G. (1985) Laboratory Evaluation of ANTEC "Virkon S" Disinfectant as a Virucidal Agent Against Avian Influenza Virus. Unpublished study prepared by Ministry of Agriculture, Fisheries and Food. 7 p. Trade Secret Status: Document Contains CBI Submitter: ANTEC INTERNATIONAL LTD Submitter No. Submission Date Accession No. 062432 01/07/04 461660 18 Administrative No: 062432-1 Laboratory No.: 062432 ANTEC INTERNATIONAL LTD 080063 MINISTRY OF AGRICULTURE, FISHERIES AND FOOD *** Chemistry Indexing *** SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide Sodium chloride (13905) SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide Potassium peroxymonosulfate (63604) *** Subject Indexing *** ROOT DT: 1005 Pesticide Use - Product Performance (Efficacy) CONTENT CATEGORY: Complete Primary Report -- Experimental Research DT SITE: UNSPECIFIED SITES (DISINFECTANTS ONLY) *** Key Author Information *** DOCUMENT TYPE: Unpublished Monograph AUTHOR: PARSONS/G TITLE: Laboratory Evaluation DATE: 11/26/85 NO related Documents for MRID: 46166018

EPA Reg No. 62432-1 was transferred to 71654-6 on Nov. 1, 2004

acceptable

46498608 Miller, M. (2005) H-26819 and H-26820: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces (Influenza A Virus): Final Study Report. Project Number: A02681, DCSE/2005/009, DUP01122804/FLUA. Unpublished study prepared by ATS Labs. 15 p. Trade Secret Status: Document Contains CBI Submitter: E.I. DUPONT DE NEMOURS AND COMPANY Submitter No. Submission Date Accession No. 071654 03/16/05 464986 08 Administrative No: 071654-7 Laboratory No.: 071654 E.I. DUPONT DE NEMOURS AND COMPANY 080995 ATS LABS Lab Project No.: A02681 DCSE/2005/009 DUP01122804/FLUA *** Chemistry Indexing *** SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide Potassium peroxymonosulfate (63604) SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide Sodium chloride (13905) *** Subject Indexing *** ROOT DT: 1005 Pesticide Use - Product Performance (Efficacy) GUIDELINE: 91-2 CONTENT CATEGORY: Complete Primary Report -- Experimental Research DT SITE: UNSPECIFIED SITES (DISINFECTANTS ONLY) ROOT DT: 1005 Pesticide Use - Product Performance (Efficacy) GUIDELINE: 91-2 CONTENT CATEGORY: Complete Primary Report -- Experimental Research DT SITE: HARD NON-POROUS SURFACE TREATMENTS *** Key Author Information *** DOCUMENT TYPE: Unpublished Monograph AUTHOR: MILLER/M TITLE: H-26819 and H-26820: DATE: 03/07/05 NO related Documents for MRID: 46498608

EPA Reg No. 71654-7 has the same formulations (basic and alternates) as 71654-6.

Tom McEntee
978 312 1160 NEW PHONE
978 335 8055 CELL

*EPA # 71654-7 an "SDO list" for approved
EPA regts for H1N1*

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http://www.DuPont.com/corp/email_disclaimer.html



DuPont Chemical Solutions Enterprise

November 11, 2009

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Sharon Carlisle (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Notification per Pandemic 2009 H1N1 Influenza Policy

Dear Ms. Carlisle,

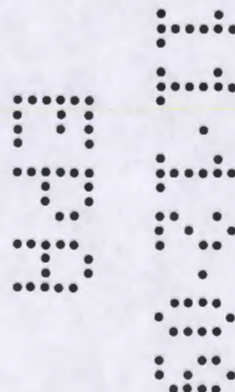
Please consider this letter and its attachments as a notification to revise the subject registration to include a claim for efficacy against Swine Influenza A (H1N1) Virus.

Should you have any questions, feel free to call or e-mail.

Sincerely,

A handwritten signature in blue ink, reading "Thomas C. McEntee".

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856



TRANSMITTAL DOCUMENT

Attention:

Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
2777 South Crystal Drive
Arlington, VA 22202-4501

NAME AND ADDRESS OF SUBMITTER

E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL402/3224A)
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

Notification to add a claim for Efficacy against Pandemic 2009 Influenza A H1N1 Virus

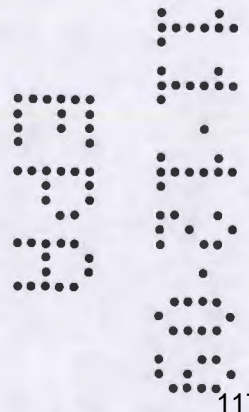
"Virkon®"; EPA Registration No. 71654-7

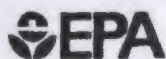
Transmittal Date: November 11, 2009

Transmittal Material:

| | | |
|----------|---|-----------|
| Volume 1 | Administrative Materials | |
| | -Cover Letter | 1 page |
| | -Application for Pesticide Registration (EPA Form 8570-1) | 1 page |
| | -Transmittal Document | this page |
| | -Printed Labeling | 13 pages |
| | -Highlighted Label Indicating Changes | 13 pages |
| | -071654-00006.20091111.Virkon S.Container H1N1.pdf | 1 CD |

.....





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|--|
| 1. Company/Product Number 71654-6 | 2. EPA Product Manager Sharon Carlisle | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Virkon(R) S | PM# 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company DuPont Chemical Solutions Enterprise, P. O. Box 80402 Experimental Station (ESL 402/3442A) Wilmington, DE 19880-0402 <input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification - Label claims in accordance with Pandemic 2009 H1N1 Influenza Policy October 21, 2009. <http://www.epa.gov/oppad001/h1n1-guide.html>

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulation at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for the product. I understand that it is a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-19 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

| | | | | | |
|--|---|--|-------------------|---|-------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | | <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ | |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt. | No. per container |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 10 lb., 1lb., 9 oz., 1.3 oz. | | 5. Location of Label Directions <input checked="" type="checkbox"/> | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | | | |

Section - IV

| | | |
|---|--|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Thomas C. McEntee | Title Product Registration Manager | Telephone No. (Include Area Code) 302 695 6856 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title Product Registration Manager | |
| 4. Typed Name Thomas C. McEntee | 5. Date November 11, 2009 | |

Material to be added to an e-Jacket/Jacket

Reg. No. 71654-6

1. ☒ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top/newest)
 - ☐ Description: (PDF page number, i.e., "before page 45")
- _____
- _____

2. ☒ Send to Data Extraction contractors this material:

☐ Newly stamped accepted label

☐ Notification

☒ New CSF

☐ Other: please add material to file

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Hacey GRIGSBY

Phone: 305-6440 Division: AD

Date: 10/16/09

RISK ASSIGNMENT FORM I
Antimicrobial Division/Regulatory Management Branch II

| | | | | | | | |
|---|--|-------------------------------------|-----------------------------------|-------------------------------------|--|--|--------------------------------|
| A | Completed by Product Manager | | | | | | |
| PRODUCT REVIEWER: | | | | | | RMB <u>II</u> TEAM <u>34</u> | |
| Description of Action: | | | | | | EPA File Symbol/Reg No. | |
| <i>Stacey Grigsby</i> <i>CSF Amendment</i> | | | | | | <i>71654-6</i> | |
| Decision No. <i>417822</i> | | Submission No. <i>854878</i> | | Fee for Service Action Code: | | | |
| FQPA Action Code: <i>362</i> | | Non-FQPA Action Code: | | PRIA FEE AMOUNT: \$ | | | |
| | MONTH | DAY | YEAR | | | | |
| APPLICATION DATE | <i>7</i> | <i>13</i> | <i>2009</i> | | | | |
| EPA PIN DATE | <i>7</i> | <i>20</i> | <i>2009</i> | | | | |
| DATE PM RECEIVED FROM FRONT-END | | | <i>2009</i> | | | | |
| Date sent to Reviewer | | | <i>2009</i> | | | | |
| DATE SENT TO SCIENCE <small>(VIVIAN COMPLETES)</small> | | | <i>2009</i> | | | | |
| DATE RECEIVED FROM SCIENCE | | | | | | | |
| NEGOTIATED DUE DATE | | | | DATE DUE OUT OF AGENCY | | <i>Oct 18, 2009</i> | |
| Type of Data: | PSB Product Chemistry <div style="text-align: center;">✓</div> | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure /Residue |
| COMMENTS: <i>Please review alternate formulas.</i> | | | | | | | |
| ATTACHMENTS: <input type="checkbox"/> -LABELING <input type="checkbox"/> -CSF(S) <input type="checkbox"/> -DATA <input type="checkbox"/> -OTHERS | | | | | | | |
| DATE FEE PAID: | | | RESPONSE CODE: <i>1155</i> | | RESPONSE DATE: <i>OCT 16 2009</i> | | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, DC 20460

OCT 16 2009

 OFFICE OF
 PREVENTION, PESTICIDES
 AND TOXIC SUBSTANCES

 Thomas McEntee
 DuPont Chemical Solutions Enterprise
 P.O. Box 80402
 Wilmington, DE 19880-0402

 Subject: **Virkon® S**
 EPA Registration No.: 71654-6
 Application Date: July 13, 2009
 Receipt Date: July 20, 2009

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3(c)7a, as amended, is acceptable.

Proposed Amendment:

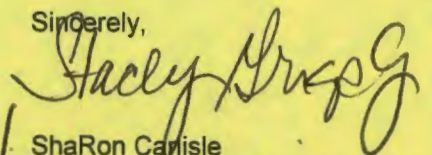
- Revise Alternate Confidential Statement of Formulas (CSFs)

General Comment:

The alternate formulations #13, 14, 15, 15.1, 16, 17 and 18, dated 7/13/09 are acceptable. Copies of the accepted CSFs have been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6427 or by e-mail at carlisle.sharon@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov during the hours of 8:00am to 4:00pm EST.

Sincerely,


 Sharon Carlisle
 (Acting) Product Manager (34)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

CONCURRENCES

| SYMBOL | | | | | | | | |
|---------|--|--|--|--|--|--|--|--|
| SURNAME | | | | | | | | |
| DATE | | | | | | | | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

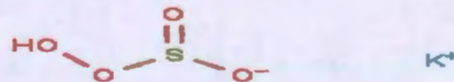
October 01, 2009

DP BARCODE: D367642
MRID: N/A
SUBJECT: Virkon® S
REG. NO. OR FILE SYMBOL: 71654-6
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes)

Sodium Chloride (013905)

Potassium peroxymonosulfate (063604)



CAS Number: (764-14-5), (10058-23-8)
TEST LAB: N/A
SUBMITTER: E.I. DuPont de Nemours and Company
GUIDELINE: N/A
COMMODITIES: Formulation
REVIEWER: Juan F. Negrón
ORGANIZATION: AD
APPROVER: Karen P. Hicks
APPROVED DATE: 10/01/09
COMMENTS:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

October 01, 2009

Subject: Product Chemistry Review for EPA Reg # 71654-6

From: Juan F. Negrón, Chemist *JFN*
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P) *KPH*

To: ShaRon Carlisle / Tracy Lantz
PM Team 34
Antimicrobials Division (7510P)

APPLICANT: E.I. Dupont de Nemours and Company

Action code: 362

Due date: 10/18/09

| Product Formulation Active Ingredient | % by wt. |
|--|----------|
|--|----------|

| | |
|----------------------------------|-------|
| Potassium peroxymonosulfate..... | 21.41 |
| Sodium Chloride..... | 1.50 |

BACKGROUND:

The registrant, E.I. DuPont de Nemours and Company, is responding to the Agency letter, dated 06/02/09, and submitted alternate formulations as an amendment for review. The integrated end-use product, VIRKON ® S, is used for cleaning and disinfecting industrial, animal and agricultural facilities. The Product Chemistry Reviewer has received the following documents:

- A transmittal document, dated 06/17/09.
- Confidential Statement of Formula, dated 01/05/04
- Confidential Statements of Formula (CSFs), dated 01/05/04, 06/17/09, & 07/13/09, for the basic and alternate #s (1, 2a, 3, 4, 5, 6, 6.1, 7, 7.1, 8, 8.1, 9, 9.1, 10, 10.1, 11, 11.1, 12, 12.1, 13, 14, 15, 15.1, 16, 17, 18) formulations.
- A letter, dated 06/17/09

FINDINGS:

1. The CSFs, dated 01/05/04, 06/17/09, for the basic and alternate #s (1, 2A, 3, 4, 5, 6, 6.1, 7, 7.1, 8, 8.1, 9, 9.1, 10, 10.1, 11, 11.1, 12, and 12.1) formulations are for reference only.
2. The CSFs, dated 07/13/09, for alternate #s (13, 14, 15, 15.1, 16, 17, and 18) formulations are revised.
3. The CSFs and the label have the same nominal.
4. All certified limits meet the EPA standard certified limits.
5. See confidential appendix CBI.

CONCLUSIONS:

The CSFs, dated 07/13/09, for alternate #s (13, 14, 15, 15.1, 16, 17, and 18) formulations are acceptable. The proposed amendment is acceptable.

Confidential Appendix CBI

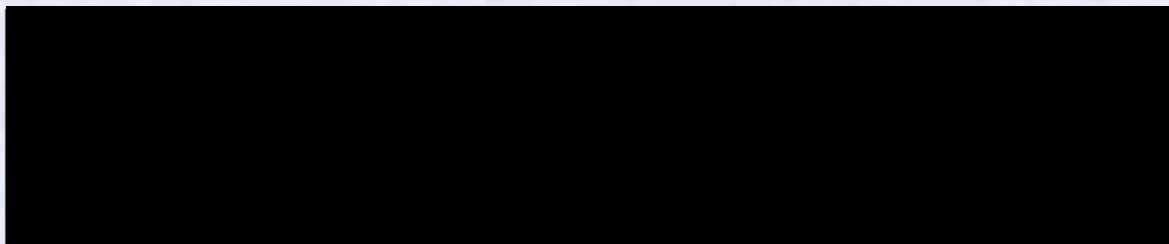
DP # 367642

EPA Reg # 71654-6

Virkon® S

FINDINGS:

5.



Material to be added to an e-Jacket/Jacket

Reg. No. 71654-6

1. ☒ Placement within the e-Jacket/jacket:

☒ Default: (chronological, top/newest)

☐ Description: (PDF page number, i.e., "before page 45")

2. ☐ Send to Data Extraction contractors this material:

☐ Newly stamped accepted label

☐ Notification

☒ New CSF

☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: L McKelne

Phone: _____ Division: AD

Date: 9-21-05

Created July 21/2008

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

| | | | | | | | |
|--|---|-------------------------------------|-----------------------------------|-------------------------------------|--------------------------------------|--|-------------------------------|
| A | Completed by Product Manager | | | | | | |
| PRODUCT REVIEWER: Lisa McKelvin | | | | | | RMB <u>II</u> TEAM <u>34</u> | |
| Description of Action: Amendment – Response to letter dated June 2, 2009 | | | | | | EPA File Symbol/Reg No. 71654-6 | |
| Decision No. <u>416543</u> | | Submission No. <u>853228</u> | | Fee for Service Action Code: | | | |
| FQPA Action Code: 362 | | Non-FQPA Action Code: | | PRIA FEE AMOUNT: \$ | | | |
| | MONTH | DAY | YEAR | | | | |
| APPLICATION DATE | June | 17 | 2009 | | | | |
| EPA PIN DATE | June | 23 | 2009 | | | | |
| DATE PM RECEIVED FROM FRONT END | June | 25 | 2009 | | | | |
| Date sent to Reviewer | July | 1 | 2009 | | | | |
| DATE SENT TO SCIENCE [VIVIAN COMPLETES] | | | 2009 | | | | |
| DATE RECEIVED FROM SCIENCE | | | | | | | |
| NEGOTIATED DUE DATE | | | | DATE DUE OUT OF AGENCY | <u>Sept 21, 2009</u> | | |
| Type of Data: | PSB Product Chemistry <input checked="" type="checkbox"/> | PSB Acute Toxicology | PSB Efficacy | RASSB Environmental Fate | RASSB Ecological Effects | RASSB Chronic Toxicology | RASSB Exposure/Residue |
| COMMENTS: Revised CSFs | | | | | | | |
| ATTACHMENTS: <input type="checkbox"/> -LABELING <input checked="" type="checkbox"/> -CSF(S) <input type="checkbox"/> -DATA <input type="checkbox"/> -OTHERS | | | | | | | |
| DATE FEE PAID: | | | RESPONSE CODE: <u>1130</u> | | RESPONSE DATE: <u>9/21/09</u> | | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

SEP 21 2009

OFFICE OF
PREVENTION, PESTICIDE
AND TOXIC SUBSTANCES

Thomas C. McEntee
Product Registration Manager
DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon® S**
EPA Registration Number: 71654-6
Letter Dated: June 17, 2009
Receipt Date: June 23, 2009

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is not acceptable for the following reasons.

Proposed Amendment

Alternate Confidential Statement of Formulas (CSFs) # 1,
2A,3,4,5,6,6.1,7,7.1,8,8.1,9,9.1,10,10.1,11,11.1,12 and 12.1 (see CSFs dated 6/17/09)

CSF Deficiencies

1. The amounts on the CSFs #8 and 8.1 must be corrected to [REDACTED].
2. The EPA CSF check sheets submitted is not acceptable. You must use EPA's form 8570-4 when submitting changes.

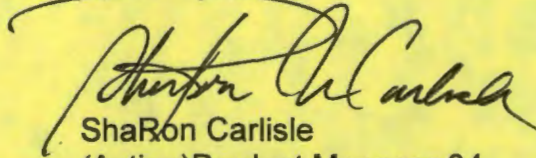
General Comment

The alternate CSFs) # 1, 2A,3,4,5,6,6.1,7,7.1,8,8.1,9,9.1,10,10.1,11,11.1,12 and 12.1 dated 6/17/09 are acceptable and have been inserted in your file for future reference.

Manufacturing process information may be entitled to confidential treatment

Should you have any questions concerning this letter, please contact me at (703) 308-6427 or via email at carlisle.sharon@epa.gov or Lisa McKelvin at (703) 308-7496 or via email at mckelvin.lisa@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sharon Carlisle', with a large, sweeping flourish extending from the end of the name.

ShaRon Carlisle
(Acting)Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

August 03, 2009

DP BARCODE: D366864
MRID: N/A
SUBJECT: Virkon® S
REG. NO. OR FILE SYMBOL: 71654-6
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes)

Sodium Chloride (013905)

Potassium peroxymonosulfate (063604)



CAS Number: 764-14-5, 10058-23-8
TEST LAB: N/A
SUBMITTER: E.I. DuPont de Nemours and Company
GUIDELINE: N/A
COMMODITIES: Formulation
REVIEWER: Salvador Rodríguez
ORGANIZATION: AD
APPROVER: Karen P. Hicks
APPROVED DATE: 08/03/09



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

August 03, 2009

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 71654-6

From: Salvador Rodríguez, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Lisa McKelvin/ Tracy Lantz
PM Team 34
Antimicrobials Division (7510P)

APPLICANT: E.I. Dupont de Nemours and Company

Action code: 362

Due date: 09/21/09

Product Formulation % by wt.

Active Ingredient Potassium peroxydisulfate..... 21.41
Sodium Chloride.....1.5

BACKGROUND:

The registrant, E.I. du Pont de Nemours and Company, has submitted Confidential Statements of Formula for the basic formulations # (1, 2A, 3, 4, 5, 6, 6.1, 7, 7.1, 8, 8.1, 9, 9.1, 10, 10.1, 11, 11.1, 12, and 12.1) for the non-integrated end-use product, **Virkon® S**. The registrant is requesting for accelerated review of minor formulation changes. The Product Chemistry Reviewer has received the following documents:

- A transmittal document, dated 06/17/2009.
- Confidential Statement of Formula, dated 01/05/04
- Confidential Statements of Formula (CSFs), dated 06/17/2009, for alternate # (1, 2a, 3, 4, 5, 6, 6.1, 7, 7.1, 8, 8.1, 9, 9.1, 10, 10.1, 11, 11.1, 12, and 12.1) formulations.
- A cover letter, dated 06/17/2009
- A list of the suppliers for substitute inserts, dated 10/30/2007 and 05/04/2009
- Confidential Statement of Formula in a different format.

FINDINGS:

1. The CSFs, dated 06/17/2009, for alternate # (1, 2A, 3, 4, 5, 6, 6.1, 7, 7.1, 8, 8.1, 9, 9.1, 10, 10.1, 11, 11.1, 12, and 12.1) formulations are revised.
2. The CSF, dated 01/05/2004, is used as reference.
3. The CSFs and the label have the same nominal.
4. All certified limits meet the EPA standard certified limits.
5. The CSFs, # 8 and 8.1, show in box # 17 a total weight of [REDACTED]. The correct amount is [REDACTED].
6. One attachment submitted is in a different format than the EPA's format 8570-4, and it is not acceptable.

CONCLUSIONS:

The CSFs, dated 06/17/2009, for alternate # (1, 2A, 3, 4, 5, 6, 6.1, 7, 7.1, 8, 8.1, 9, 9.1, 10, 10.1, 11, 11.1, 12, and 12.1) formulations are acceptable. The proposed technical amendment is acceptable.

RECOMMEDATION:

- The registrant must modify the total weight in box # 17. See finding # 5
- The registrant must use the EPA's form 8570-4 to submit any data regarding CSFs information. See finding #6.

Manufacturing process information may be entitled to confidential treatment

34

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



DuPont Chemical Solutions Enterprise

July 13, 2009

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Tracy Lantz (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Notification per PR Notice 98-10 III.D.

Dear Ms. Lantz

Please consider this letter and its attachments as a NOTIFICATION under PR Notice 98-10 III.D.

I am resubmitting the attached formulas to indicate a specific US producer and for one formula the legacy UK producer. The attached formulas were first submitted on August 2, 2007 and accepted according to the attached letter from Adam Heyward on November 8, 2007. I have revised the current submission to reflect the actual producing location.

Following my submission of June 17, 2009, I have re-designated the CSF's submitted today to a follow-on sequence e.g. the Aug. 2, 2007 Alt.# 1 has been re-named Alt #13 (following Alt. #12.1 of the June 17, 2009 series).

None of the formulas have been changed from the Aug. 2, 2007 declaration.

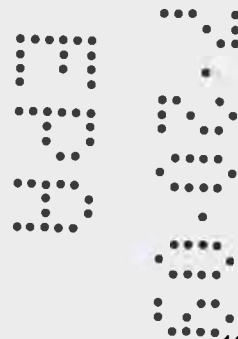
No intent is made to supersede any previously accepted formula.

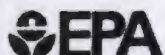
Should you have any questions, feel free to call or e-mail.

Sincerely,

A handwritten signature in dark ink, appearing to read "Thomas C. McEntee", written in a cursive style.

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|--|--|
| 1. Company/Product Number 71654-6 | 2. EPA Product Manager Tracy Lantz | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Virkon S (R) | PM# 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company Attn: Thomas C. McEntee Dupont Chemical Solutions Enterprise, P. O. Box 80402 Wilmington, DE 19880-0402 <input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

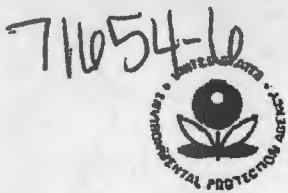
Clarify producing Establishment location (Block #2) on previously accepted compositions.
Re-designated Alternates #13 thru #18.

Section - III

| | | | | | |
|---|--|---|---|--|--|
| 1. Material This Product Will Be Packaged In: | | | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ | | |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. No. per container | If "Yes" Package wgt. No. per container | | |
| | | 1.3 oz. | 50 | | |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 10 lb., 4 lb, 1lb., 9 oz., | | 5. Location of Label Directions <input checked="" type="checkbox"/> | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____ | | | | | |

Section - IV

| | | | |
|--|--|---|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name Thomas C. McEntee | | Title Product Registration Manager | |
| | | Telephone No. (Include Area Code) 302 695 6856 | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received (Stamped) |
| 2. Signature Thomas C. McEntee / KOG | | 3. Title Product Registration Manager | |
| 4. Typed Name Thomas C. McEntee | | 5. Date July 13, 2009 | |



7/1/2009

10f16

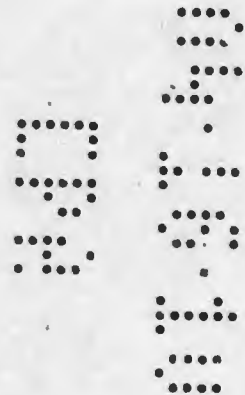
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUL 1 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Bonnie J. Bieber
Regulatory Coordinator
E.I. du Pont de Nemours and Company
DuPont Chemical Solution Enterprise
P.O. Box 80402 (E403-3224D)
Wilmington, DE 19880-0402

Subject: Notification in Accordance with PR Notice 98-10
Virkon® S
EPA Registration No. 71654-6
Application Date: June 3, 2009
Receipt Date: June 8, 2009



Dear Ms. Bieber:

This acknowledges receipt of your application, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

Label change due to PR Notice 2007-4

General Comments

Based on a review of the material submitted, the following comments apply:

The notification is acceptable and a copy has been inserted in your file for future reference.

At your next label amendment amendment you must change *Salmonella Choleraesuis* to *Salmonella enterica*.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6415 or email address at: lantz.tracy@epa.gov or Renae Whitaker by telephone at (703) 308-7003 or email at whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Tracy Lantz
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)



DuPont Chemical Solutions Enterprise

June 17, 2009

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Tracy Lantz (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Amendment; PR 98-10 V.A.1, 2 or 3
Reference Your letter of June 2, 2009

Dear Ms. Lantz

Please consider this letter and its attachments as a request for ACCELERATED REVIEW OF MINOR FORMULATION CHANGES under PR Notice 98-10 V.A.1, 2 and 3.

Following your letter of June 2, 2009, I have resubmitted the alternate formulas as amended formulas rather than notification.

In order to be consistent with the PC codes used in NPIRS, I have uniformly changed the Chemical Abstracts Number for the active ingredient, potassium peroxymonosulfate to CAS # 10058-23-8.

Regarding acceptance of a formula with [REDACTED] as a fragrance ingredient, please refer to the attached CSF COPY dated January 5, 2004, which was accepted by Adam Heyward October 21, 2004.

Should you have any questions, feel free to call or e-mail.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856

Inert ingredient information may be entitled to confidential treatment

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



DuPont Chemical Solutions Enterprise

June 17, 2009

Document Processing Desk
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs; Room S-4900
Ms. Tracy Lantz (PM34)
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Virkon® S; EPA Registration No. 71654-6
Amendment; PR 98-10 V.A.1, 2 or 3
Reference Your letter of June 2, 2009

Dear Ms. Lantz

Please consider this letter and its attachments as a request for ACCELERATED REVIEW OF MINOR FORMULATION CHANGES under PR Notice 98-10 V.A.1, 2 and 3.

Following your letter of June 2, 2009, I have resubmitted the alternate formulas as amended formulas rather than notification.

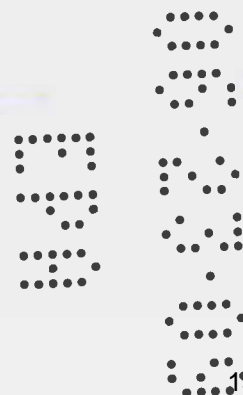
In order to be consistent with the PC codes used in NPIRS, I have uniformly changed the Chemical Abstracts Number for the active ingredient, potassium peroxymonosulfate to CAS # 10058-23-8.

Regarding acceptance of a formula with [REDACTED] as a fragrance ingredient, please refer to the attached CSF COPY dated January 5, 2004, which was accepted by Adam Heyward October 21, 2004.

Should you have any questions, feel free to call or e-mail.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695-6856



Manufacturing process information may be entitled to confidential treatment

Ms. Tracy Lantz
Antimicrobials Division (7510P)
US Environmental Protection Agency
Office of Pesticide Programs
Room S 4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL402/3224C)
P. O. Box 80023
Wilmington, DE 19880-0402**

**REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-
Amendment – Accelerated Review of Minor Changes per PR Notice 98-10 - Adjust batch
size - for producing locations (Block #2) and country where formulated (Block #6.)
Previously accepted alternate formulas**

"Virkon® S"; EPA Registration No. 71654-6

Transmittal Date: **June 17, 2009****Volume 1 Administrative Materials**

-Cover Letter

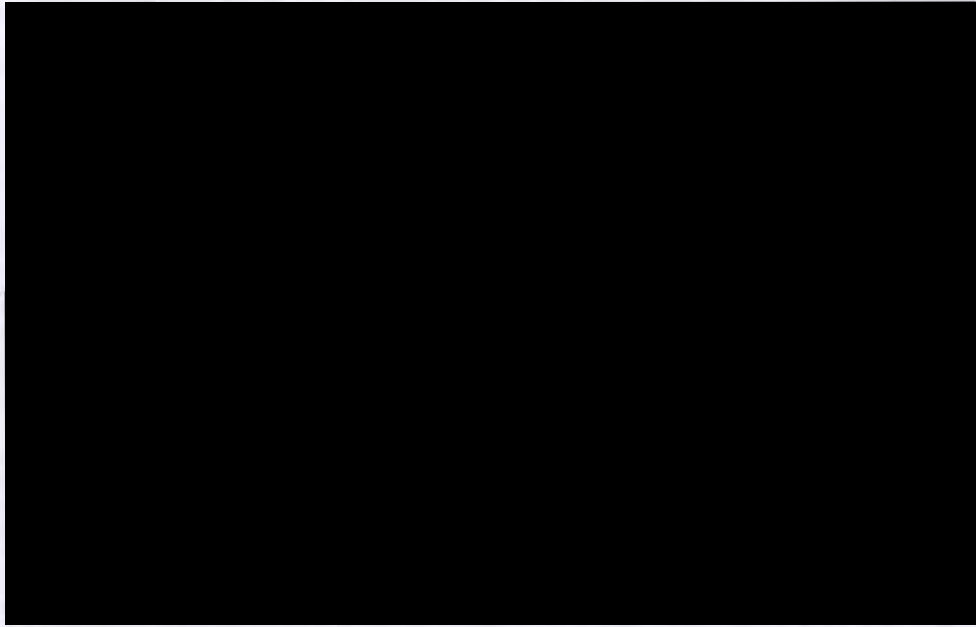
-Application for Pesticide Registration (EPA Form 8570-1)

-Transmittal Document

1 page

1 page

this page



2016

**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other: NOTIFICATION

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|---|---|
| 1. Company/Product Number 71654-6 | 2. EPA Product Manager Emily Mitchell | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Virkon S | PM# Team 32 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company DuPont Chemical Solutions Enterprise P.O. Box 80402 (E403-3224D) Wilmington, DE 19880-0402 Attn: Bonnie J. Bieber | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |
| <input type="checkbox"/> Check if this is a new address | | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**"Notification of label change per PR Notice 2007-4."**

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

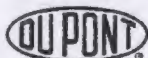
| | | | | | |
|--|---|--|--------------------------|---|--|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | | <input type="checkbox"/> Metal | |
| | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt. | No. per container | <input type="checkbox"/> Plastic |
| *Certification must be submitted | | | | | <input type="checkbox"/> Glass |
| | | | | | <input type="checkbox"/> Paper |
| | | | | | <input type="checkbox"/> Other (Specify) |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product | | <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ | | | |
| <input type="checkbox"/> Paper glued | | <input type="checkbox"/> Stenciled | | | |

Section - IV

| | | |
|--|---|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) | | |
| Name Bonnie J. Bieber | Title Regulatory Coordinator | Telephone No. (Include Area Code) (302) 695-1557 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title Regulatory Coordinator | |
| 4. Typed Name Bonnie J. Bieber | 5. Date 6/2/09 | |

30916

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



DuPont Chemical Solutions Enterprise

June 3, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard)
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: Virkon S
EPA Registration #: 71654-6
Notification of label change per PR Notice 2007-4

Dear Sir or Madam:

In accordance with PR Notice 2007-4, E.I. du Pont de Nemours and Company is notifying the Agency of Storage and Disposal Language label language upgrades for the above referenced product. Attached please find the following documents supporting this notification:

- Application for Pesticide Registration (EPA form 8570-1) – dated 6/3/09
- One copy of the label with changes highlighted

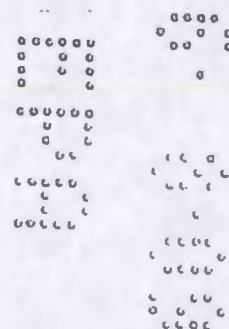
This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Please contact me by phone at 302-695-1557 or by email at bonnie.j.bieber@usa.dupont.com if you have any questions.

Sincerely,

Bonnie J. Bieber
Regulatory Coordinator,
E.I. DuPont de Nemours and Company
DuPont Chemical Solutions Enterprise

attachments





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 22, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-394021
EPA File Symbol or Registration Number: 71654-6
Product Name: VIRKON S
EPA Receipt Date: 20-May-2008
EPA Company Number: 71654
Company Name: E.I. DUPONT DE NEMOURS AND COMPANY

BONNIE J. BIEBER
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A440

NEW USE;FIRST FOOD USE;WITH EXEMPTION;Reduced Fee: Linked to PRIA Application;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff
Information Technology & Resources Management Division

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

| EPA Receipt Date: MAY 20 2008 | | EPA Reg. Number: 71654-6 | | |
|--------------------------------------|---|---------------------------------|----|-----|
| | Check List Item | Yes | No | N/A |
| 1 | Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package? | X | | |
| 2 | Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type? | X | | |
| 3 | Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)? | | X | |
| 4 | Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package? | | X | |
| 5 | Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package? | X | | |
| 6 | Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package? | X | | |
| 7 | Is a Label Included in the Submission Package? | X | | |
| 8 | Are Data Included in the Submission Package? | | X | |
| 9 | Is the Submission an Amendment? | X | | |

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/25/08

21 Day Screen Start Date: _____

Experts In-Processing Signature: _____

Date _____

Fee Paid: Yes ☒

Division contacted on issues No _____ Yes _____

Date _____

| EPA Reg. Number: 716546 | | EPA Receipt Date: 5/20/08 | | | | | | | |
|--------------------------------|---|-------------------------------------|-------------------------------------|-------------------------------------|----|-------------------------------------|-------------------------------------|--|--|
| Items for Review | | | | Yes | No | N/A* | | | |
| 1 | Application Form (EPA Form 8570-1) signed & complete including package type | | | <input checked="" type="checkbox"/> | | | | | |
| 2 | Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) | | | | | <input checked="" type="checkbox"/> | | | |
| | | yes | no | | | | | | |
| | a) All inerts, except fragrances, approved for food and non food proposed uses (see Footnote A) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | | | | |
| 3 | Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack) | | | <input checked="" type="checkbox"/> | | | | | |
| | Certificate and data matrix consistent | | | <input checked="" type="checkbox"/> | | | | | |
| | | yes | no | | | | | | |
| | If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) N/A | | | | | | | | |
| | If applicable, is there a letter of Authorization for exclusive use only. | | | | | | | | |
| 4 | Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical) | | | | | <input checked="" type="checkbox"/> | | | |
| | Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack) | | | <input checked="" type="checkbox"/> | | | | | |
| | | yes | no | | | | | | |
| 5 | a) Selective Method (Fee category experts use) | <input checked="" type="checkbox"/> | | | | | | | |
| | b) Cite-All (Fee category experts use) | | | | | | | | |
| | c) Applicant owns all data (Fee category experts use) | | | | | | | | |
| 6 | Copies of Label | | | | | | <input checked="" type="checkbox"/> | | |
| 7 | Is the data package consistent with PR Notice 86-5 | | | | | | <input checked="" type="checkbox"/> | | |
| 8 | Notice of Filing included with petitions | | | <input checked="" type="checkbox"/> | | | | | |

Fee for Service

W
{829500V~

This package includes the following

New Registration

• **Amendment**

Studies? Fee Waiver?

volpay % Reduction: _____

for Division

• **AD**
BPPD
RD

Risk Mgr. 34

Receipt No.

S- 829500

EPA File Symbol/Reg. No.

71654-6

Pin-Punch Date:

5/20/2008

☐ **This item is NOT subject to FFS action.**

Action Code:

Requested: A440

Granted: A440

Amount Due: \$ 26,250

Parent/Child Decisions:

Inert Cleared for Intended Use

Uncleared Inert in Product

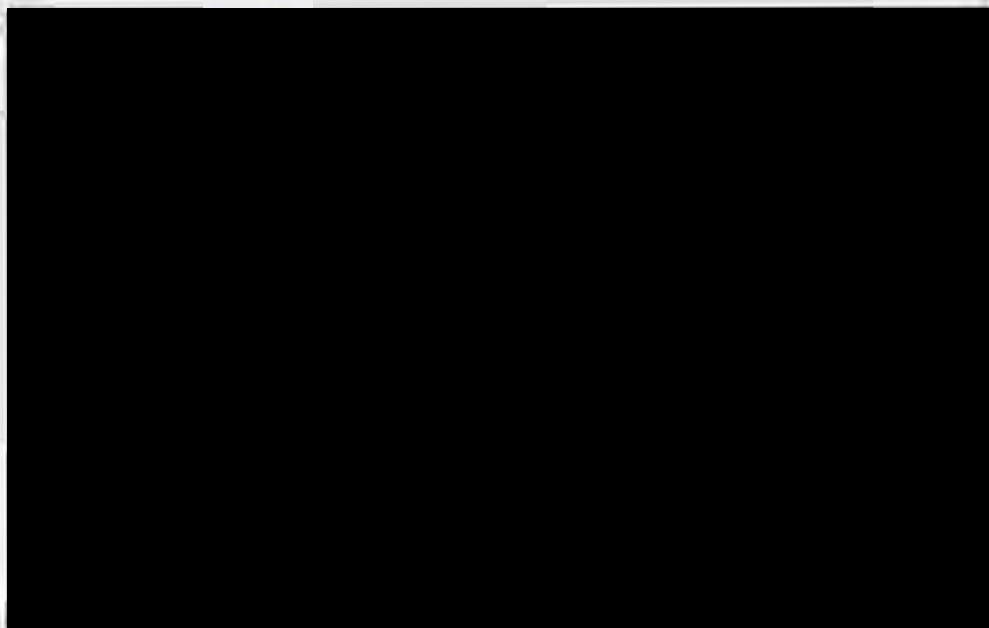
Reviewer: Mail Team 3

Date: 5/22/08

Remarks: Sec. 3 related to tolerance petition # 8F7360

Manufacturing process information may be entitled to confidential treatment

101.24





The MSDS format adheres to the standards and regulatory requirements of the United States and may not meet regulatory requirements in other countries.

DuPont
Material Safety Data Sheet

Page 1

Virkon(R) S
ANTEC03 Revised 18-AUG-2006

CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Product Use

Animal Premises' Disinfectant and Cleaner

Tradenames and Synonyms

"Virkon" is a registered trademark of Antec(tm) Int'l Ltd.

Company Identification

MANUFACTURER/DISTRIBUTOR

DuPont Chemical Solutions Enterprise
1007 Market Street
Wilmington, DE 19898

PHONE NUMBERS

Product Information : 1-800-441-7515 (outside the U.S. :
302-774-1000)
Transport Emergency : CHEMTREC 1-800-424-9300(outside U.S.:
703-527-3887)
Medical Emergency : 1-800-441-3637 (outside the U.S. :
302-774-1000)

COMPOSITION/INFORMATION ON INGREDIENTS

Components

| Material | CAS Number | % |
|-----------------------------|------------|---|
| Potassium Peroxymonosulfate | 70693-62-8 | |
| Sulfamic Acid | 5329-14-6 | |
| Sodium Chloride | 7647-14-5 | |

Unique Label Statements

KEEP OUT OF REACH OF CHILDREN *****

HAZARDS IDENTIFICATION

Potential Health Effects

Skin contact with product diluted in water according to package directions (1% solution) is not a skin irritant. Skin contact with dry powder may cause skin burns or ulceration. In rare cases, skin contact with dry powder may cause an allergic skin reaction in sensitive individuals.

Eye contact with product diluted in water according to

(HAZARDS IDENTIFICATION - Continued)

package directions (1% solution) is not an eye irritant. Eye contact with dry powder may cause eye corrosion or ulceration. Severe eye damage may result if not immediately treated.

Inhalation of this product may cause nose bleed or irritation of the upper respiratory passages, with coughing, sneezing, runny nose and sore throat. Gross overexposure may cause ulceration of mucous membranes.

Ingestion of this product may cause gastritis, with stomach pain, nausea, vomiting, diarrhea, headache or weakness; possibly progressing to necrosis or hemorrhage with gross overexposure.

Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

FIRST AID MEASURES

First Aid

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for further treatment advice.

IF IN EYES: Hold eye open & rinse slowly & gently with water for 15-20 minutes. Remove contact lenses, if present after 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for further treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further treatment advice.

IF SWALLOWED: Call Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

FIRE FIGHTING MEASURES

Extinguishing Media

Dry Powder (Sand or Met-L-X), CO2.

Fire Fighting Instructions

Evacuate personnel to a safe area. Wear self-contained breathing apparatus (SCBA) and full protective equipment.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

Spill Clean Up

Sweep, shovel, vacuum or scoop up into suitable containers for disposal. Prevent powder from becoming moist while awaiting disposal. Moist product must be kept away from combustible material and stored in a manner that allows suitable ventilation of the waste.

HANDLING AND STORAGE

Handling (Personnel)

Do not get in eyes, on skin or clothing. Avoid breathing dust. Wash thoroughly after handling. Wash contaminated clothing prior to reuse.

Storage

Store in a cool, dry place.

Keep containers tightly sealed and avoid coming into contact with moisture.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

Use only with adequate ventilation.

Personal Protective Equipment

EYE/FACE PROTECTION

(EXPOSURE CONTROLS/PERSONAL PROTECTION - Continued)

Wear coverall chemical splash goggles. Additionally, wear a face shield where the possibility exists for face contact due to splashing or spraying of material.

RESPIRATORS Wear NIOSH approved respiratory protection as appropriate.

PROTECTIVE CLOTHING

Where there is potential for skin contact have available and wear as appropriate impervious gloves, apron, pants, jacket, hood and boots.

Exposure Guidelines

Applicable Exposure Limits

Potassium Peroxymonosulfate

| | |
|----------------|--|
| PEL (OSHA) | : None Established |
| TLV (ACGIH) | : None Established |
| AEL * (DuPont) | : 1 mg/m ³ , 8 & 12 Hr. TWA |

Sulfamic Acid

| | |
|----------------|---|
| PEL (OSHA) | : None Established |
| TLV (ACGIH) | : None Established |
| AEL * (DuPont) | : 0.5 mg/m ³ , 8 & 12 Hr. TWA 1.5 mg/m ³ , 15 minute TWA |

* AEL is DuPont's Acceptable Exposure Limit. Where governmentally imposed occupational exposure limits which are lower than the AEL are in effect, such limits shall take precedence.

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Boiling Point: Decomposes on heating
Solubility in Water: 65 g/litre (8.2 oz/gallon) at 20 C/68 F
Form: Free flowing powder
Color: Yellow
Odor: Faint lemon
Specific Gravity: ~1.07

STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and storage conditions.

(STABILITY AND REACTIVITY - Continued)

Incompatibility with Other Materials

Incompatibility with strong alkalies and moisture. When wet reacts slowly in solution to make small amount of hypochlorous acid or hypochlorite, depending on pH.

Decomposition

Hazardous decomposition products are: sulfur dioxide and chlorine under extreme conditions if powder is allowed to become damp through incorrect storage or long exposure to the atmosphere.

Polymerization

Polymerization will not occur.

DISPOSAL CONSIDERATIONS

Waste Disposal

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

TRANSPORTATION INFORMATION

Shipping Information

Not Regulated as a hazardous material by DOT, IMO, or IATA.

REGULATORY INFORMATION

U.S. Federal Regulations

TSCA Inventory Status : Listed.

OTHER INFORMATION

Additional Information

Antec(tm) International Ltd.
A DuPont Company
Windham Road
Chilton Industrial Estates
Sudbury, Suffolk, United Kingdom CO10 2XD

Telephone: 44-(0)-1787-377305

(Continued)

EPA Reg. No. 71654-6

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

Responsible for MSDS : MSDS Coordinator
> : DuPont Chemical Solutions Enterprise
Address : Wilmington, DE 19898
Telephone : (800) 441-7515

Indicates updated section.

This information is based upon technical information believed to be reliable. It is subject to revision as additional knowledge and experience is gained.

End of MSDS

Virkon® S
Disinfectant and Virucide

BROAD SPECTRUM DISINFECTANT, FUNGICIDE & ALGAECIDE [OPT]

[Fragrance Free] [Reduced Dye] [Fragrance and Dye Free] {OPT}

For Use in Cleaning and Disinfecting Industrial, Animal and Agricultural Facilities
For Use in Emergency Disease Control [OPT]

Effective against
•Viruses
Including Canine Parvovirus [OPT]
•Bacteria
•Fungi

ACTIVE INGREDIENTS:

| | |
|----------------------------------|---------------|
| Potassium peroxymonosulfate..... | 21.41% |
| Sodium Chloride..... | 1.50% |
| OTHER INGREDIENTS..... | <u>77.09%</u> |
| TOTAL..... | 100.00% |

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

See Inside Booklet for Additional Precautions

POWDER FORM [OPT]

TABLET FORM [OPT]

SACHET FORM [OPT]

Copyright © 2006-2008 E. I. du Pont de Nemours and Company All Rights Reserved.

Virkon® S is a registered trademark of and manufactured by Antec International Ltd., a DuPont Company

EPA Reg. No. 71654-6

EPA Est. No. XXXXX-YY-ZZZ

Front Panel Continued

| FIRST AID | |
|--|--|
| If in Eyes: | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present after 5 minutes, then continue rinsing eye. • Call a Poison Control Center or doctor for further treatment advice. |
| If on Skin or Clothing: | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor for further treatment advice. |
| If Swallowed: | <ul style="list-style-type: none"> • Call Poison Control Center or doctor immediately for treatment advice. • Have Person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person |
| HOT LINE NUMBER | |
| For 24-hour emergency information on this product, call 1-800-3637 (US & Canada) or 1-302-774-1100 (all other areas). Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |
| Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. | |

Manufactured for:
E.I. DuPont de Nemours and Company
 PO Box 80023
 Wilmington, DE 19880-0023
 Questions? Call 1 800 441-7515

US Patent No. 4822512

EFFECTIVE AGAINST THE FOLLOWING PATHOGENS:**ANIMAL AND ZOONOTIC PATHOGENS****BACTERIA**

Actinobacillus pleuropneumoniae
Bacillus cereus
Brucella abortus
Campylobacter jejuni
Clostridium perfringens
Dermatophilus congolensis
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Pasteurella multocida
Pseudomonas aeruginosa
Salmonella choleraesuis
Salmonella typhimurium
Shigella sonnei
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pyogenes
Streptococcus suis

*Not approved in California for use against
the following bacteria:*

Bordetella avium
Bordetella bronchiseptica
Fistulous withers (Poll Evil)
Haemophilus somnus
Helicobacter pylori
Listeria monocytogenes
Moraxella bovis (Pink Eye)
Mycoplasma hyopneumonia
Mycoplasma mycoides
Pseudomonas mallei (Glanders)
Pseudomonas vulgaris
Streptococcus equi (Strangles)
Taylorella equigenitalis
Treponema hyodysenteriae

VIRUSES

Avian Influenza Virus
 Avian Laryngotracheitis Virus
 Bovine Adenovirus Type 4
 Canine Adenovirus (Canine Hepatitis)
 Canine Parvovirus
 Equine Herpes Virus (Type 1)
 Herpes Virus Equine (Type 3)
 Equine Influenza Virus (Type A)
 Feline Calicivirus
 Feline Panleukopenia Virus
 Feline Rhinotracheitis Virus
 Newcastle Disease Virus
 Simian virus (SV40 Virus)

Not approved in California for use against the following viruses:

Adenovirus Pneumonia
 African Horse Sickness Virus
 African Swine Fever Virus (tested with 1% soil load and 342 ppm hard water)
 Bovine Polyoma Virus
 Bovine Pseudocowpox Virus
 Bovine Viral Diarrhea Virus (no hard water)
 Calf Rotavirus (no hard water)
 Canine Coronavirus
 Canine Parainfluenza Virus
 Chicken Anemia Virus
 Coital Exanthema Virus
 Distemper Virus
 Duck Adenovirus (no hard water)
 Duck Enteritis Virus
 Egg Drop Syndrome Adenovirus
 Equine Infectious Anemia Virus (Swamp Fever)
 Equine Arteritis Virus (no hard water)

Not approved in California cont.

Hog Cholera Virus
 Equine Contagious Abortion Virus
 Equine Papillomatosis Virus
 Equine Influenza Virus (The Cough)
 Feline Herpes Virus
 Feline Infectious Peritonitis Virus
 Feline Parvovirus
 Foot and Mouth Disease Virus
 Infectious Bronchitis Virus
 Infectious Bursal Disease Virus
 Infectious Canine Hepatitis Virus
 Infectious Pancreatic Necrosis Virus
 Infectious Salmon Anaemia Virus
 Infective Bovine Rhinotracheitis Virus (no hard water)
 Leptospira Canicola Virus
 Maedi-Visna Virus
 Marek's Disease Virus
 Mouse Parvovirus
 PCV2 Virus (PMWS)
 Porcine Parvovirus
 Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
 Pseudorabies Virus (Aujeszky's Disease) (no hard water)
 Rotaviral Diarrhea Virus
 Snakehead rhabdovirus
 Swine Influenza Virus
 Swine Vesicular Disease Virus
 Transmissible Gastroenteritis Virus (TGE) (no hard water)
 Turkey Herpes Virus (no hard water)
 Turkey Rhinotracheitis Virus
 Vesicular Stomatitis Virus

80816

FUNGI

Trichophyton mentagrophytes (2%)

Not approved in California for use against the following fungi:

Aspergillus fumigatus
Fusarium moniliforme
Microsporum canis
Trichophyton spp. (Ringworm)
Trichophyton spp. (Mud Fever)

PLANT PATHOGENS

Not approved in California for use against plant pathogens:

| | |
|-------------------------|---------------------------|
| Alternaria solani | Pyrenochaeta lycoopersici |
| Botrytis cinera | Pythium aphanidermatum |
| Colletotrichum coccodes | Rhizoctonia solani |
| Didymella bryoniae | Sclerotinia sclerotiorum |
| Fusarium oxysporum | Thielaviopsis basicola |
| Fusarium solani | Verticillium dahliae |
| Penicillium oxalicum | Xanthomonas axonopodis |
| Phomopsis sclerotioides | |

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Powder is corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles (or face shield). Wear protective clothing (long sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Corrosive statement refers to powder only not in use solution.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

BROAD SPECTRUM DISINFECTANT

Virkon® S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy of the 1% solution against bacteria and viruses was determined in the presence of 400 ppm [200 ppm in California] AOAC hard water and 5% organic material in most cases. The exceptions are noted with qualifiers, e.g., "no hard water," "no soil load," and "use 2% solution."

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

GENERAL INSTRUCTIONS—POULTRY AND FARM PREMISES

1. Remove all poultry or other animals and feeds from premises, trucks or other vehicles, coops, crates or other enclosures.
2. Remove all litter droppings and manure from floors, walls and surfaces of barns pens, stalls, chutes and other facilities and fixtures occupied or traversed by poultry or other animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Virkon® S DILUTION CHART

Fill container with desired amount of water and add Virkon® S powder or tablet(s) to achieve recommended solution concentration. [For a 1% solution, add one (1) tablet to one pint of water. OPT.] [For a 1% solution, empty one 1.3 oz. sachet into 1 gallon of water. OPT]

Powder

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|---------------------|
| 1 Quart | 0.15 ounces* | 0.3 ounces | 0.7 ounces |
| 1 Gallon | 0.65 ounces* | 1.3 ounces | 2.7 ounces |
| 10 Gallons | 6.7 ounces* | 13.4 ounces | 26.7 ounces |
| 50 Gallons | 33.4 ounces* | 66.8 ounces | 133.5 ounces |

Measuring cup provided.

Tablet

| Quantity of Water | 0.5% Solution* | 1% Solution | 2% Solution |
|--------------------------|-----------------------|--------------------|--------------------|
| 1 Pint | | 1 tablet | 2 tablets |
| 1 Quart | 1 tablet* | 2 tablets | 4 tablets |
| 1 Gallon | 4 tablets* | 8 tablets | 16 tablets |

* The 0.5% solution currently is not approved for use in California.

Sachet

| <i>Quantity of Water</i> | <i>0.5% Solution*</i> | <i>1% Solution</i> | <i>2% Solution</i> |
|--------------------------|-----------------------|--------------------|--------------------|
| <i>1 gallon</i> | <i>-</i> | <i>1 Sachet</i> | <i>2 Sachets</i> |
| <i>2 Gallons</i> | <i>1 Sachet</i> | <i>2 Sachets</i> | <i>4 Sachets</i> |

* The 0.5% solution is currently not approved for use in California.

Solutions are stable for 7 days. Do not soak metal objects in Virkon® S for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft. [This powder formulation is easily diluted for use in manual or machine operations. OPT.]

POULTRY PRODUCTION AND RATITE PRODUCTION

CONTROLS: Viruses of Newcastle Disease, Avian Laryngotracheitis and Avian Influenza; Bacteria of *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Mycoplasma gallisepticum*. *Not approved in California for use against the following organisms:* Viruses of Infectious Bursal Disease, Infectious Bronchitis Virus, Marek's Disease, Egg Drop Syndrome, Turkey Herpes Virus, Duck Viral Enteritis; FUNGI (molds and yeasts) *Aspergillus flavus*, Fungi of *Aspergillus fumigatus* and Bacteria of *Bordetella avium*, *Helicobacter pylori*.

HATCHERIES: Virkon® S at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes.

Virkon® S at 1-2% solution is recommended for use in fogging (wet misting) operations as a supplemental measure, either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and pre-clean area to be treated. Spray floors and walls with Virkon® S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of Virkon® S. After contact for 10 minutes, rinse with water. Do not house poultry or use equipment until treatment has dried.

FOR AIR SANITIZING: *Not approved for this use in California:* Use Virkon® S at 0.5-1% solution, and fog until surfaces are moist. Allow at least 2 hours before entering treated area. Rinse foggers and sprayers with water following use.

PROCESSING PLANTS: Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings and floors.

SWINE PRODUCTION

CONTROLS: Bacteria of *Actinobacillus Pleuropneumoniae* and *Clostridium perfringens*; *Not approved in California for use against the following organisms:* Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Porcine Reproductive and Respiratory Syndrome Virus (PRRS); Pseudorabies, Rotoviral Diarrhea, African Swine Fever, Fungi of *Fusarium moniliforme* Foot and Mouth Disease and Bacteria of *Treponema hyodysenteriae*.

Follow General Instructions to remove swine and pre-clean area to be treated. Virkon® S at 1% solution is recommended for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. *Not approved in California for fogging at dilutions less than 1%.* Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

Aerial Disinfection in the Presence of Poultry and Swine

Spraying a fine disinfectant mist or fog in premises, even in the presence of poultry and swine can help control and prevent the spread of viruses.

Apply Virkon® S Disinfectant and Virucide at a dilution rate of 1:200 (0.5%) at an application rate of 1 gallon per 430ft² of floor space daily. Use a mechanical (cold fogger) or plumbed in misting system designed for water-based applications, with a droplet size of greater than 50 microns, or a pressure washer/knapsack or tank sprayer to deliver a very fine mist.

Thermal foggers are not recommended as the noise will disturb the birds.

Note: Individuals should avoid entering the building or room while aerial disinfection is in progress. If the building or room must be entered, then the individuals entering must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT, AND AERIAL DISINFECTION

CONTROLS: *Not approved in California for use against the following organisms:* Fungi of *Fusarium moniliforme*. Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis; Bacteria of *Clostridial Diarrhea*, *Fistulous Withers* (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders); Fungi of *Dermatophytosis* (Ringworm) and *Dermatophylosis* (Mud Fever).

APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

USES: Stables, Horse Boxes, Box Stalls, Tack, Equipment, and Feed Rooms: Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% Virkon® S solution. Rinse with clean water.

Blankets, Saddle Pads and Rugs: *Not an approved use in California:* Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue.

Aerial Spraying to control airborne diseases: *Not an approved use in California:* Use a hand or knapsack sprayer with fine setting, or an automatic spraying system. Spray a 1% Virkon® S solution for 2-3 minutes twice daily, first thing in the morning and last thing at night. Rinse sprayers with water after use.

BOVINE PRODUCTION

CONTROLS: Bovine Adenovirus Type 4; *Not approved in California for use against the following organisms:* Bacteria of *Moraxella bovis* and Fungi of *Fusarium moniliforme*. Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Pseudorabies, Foot and Mouth Disease and Bacteria of *Haemophilus somnus*.

Follow General Instructions to remove livestock and preclean area to be treated. A 1% solution of Virkon® S is recommended to clean and disinfect areas associated with bovine housing stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, water-proof footwear (such as rubber boots), and associated livestock equipment and instruments.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus and Feline calicivirus; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. *Not approved in California for use against the following organisms:* Viruses of Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes; Fungi of *Microsporum canis*.

APPLICATIONS: A 1% solution of Virkon® S is recommended as a "one step" cleaning and disinfecting procedure (Remove Gross filth and heavy soil deposits before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages [caging systems] within [associated with] Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

GREENHOUSES AND HORTICULTURE

Virkon® S is intended to disinfect inanimate environmental surfaces: such as floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. *Not approved in California for use on ventilation and other equipment and water systems.* It is not

intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.

For surfaces and equipment

- 1) Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt.
- 2) Use a dilution of 1:100 or 1.3 oz. Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits. *Not approved in California for use at 1:50 dilution on surfaces that have not been pre-cleaned with water to removed organic deposits.*
- 3) Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.
- 4) Heavy growth of algae or fungi may have to be scrubbed off following application.
- 5) Reapply as often as needed for control.

For clean non-porous surfaces

Pots, flats, trays: Use a dilution of 1:100 or 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.

Work areas: Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 or 1.3 oz. of Virkon® S per gallon of clean water. Use a dilution of 1:50 or 2.6 oz. of Virkon® S per gallon of clean water if surfaces that are to be treated have not been pre-cleaned with water to remove organic deposits.

For evaporative coolers *Not approved use in California*:: treat existing algae and slime-contaminated surfaces with a 1:100 dilution of Virkon® S. Treat cooler water every week with a dilution of 1:200 or 0.65 oz. of Virkon® S for every gallon of cooler water.

Virkon® S may also be used to disinfect irrigation tanks and lines. *Not approved use in California*: Run a 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and flush system with clean water after treatment.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

AQUACULTURE

Not approved for this use in California

Virkon® S is intended to disinfect inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes and other similar equipment. Virkon® S may also be used in foot dips. Virkon® S must not be applied directly to water.

Equipment used in separate sites, tanks, ponds in aquacultural settings should be disinfected before each new use by soaking for 20-30 minutes in a 1% Virkon® S solution followed by a water rinse.

Virkon® S at 0.5-1% solution is recommended for use in fogging (wet misting) operations or as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions. Rinse foggers and sprayers with water following use.

EMERGENCY DISEASE CONTROL (ANIMAL HEALTH)

Not approved for this use in California

CONTROLS: OIE List A Disease organisms including Foot and Mouth Disease Virus, African Horse Sickness Virus, Vesicular Stomatitis Virus, Classical Swine Fever Virus (Hog Cholera Virus), African Swine Fever Virus, Newcastle Disease Virus, and Highly Pathogenic Avian Influenza Virus, Swine Vesicular Disease Virus, and Mycoplasma mycoides (Contagious Bovine Pleuropneumonia). (OPT.)

A 1% solution of Virkon® S is recommended to clean and disinfect agricultural facilities and equipment, military facilities and equipment; airport facilities and equipment, port facilities and equipment, rail facilities and equipment, quarantine facilities and equipment, slaughter facilities and equipment, and other shipping facilities and equipment where animals or soils suspected of harboring foot and mouth disease virus might have been previously present.

Within these facilities, treated objects include but are not limited to vehicles, farm equipment (including tractors, ploughing shares, cars and trucks, farm engines, harvesters, loaders, mowers, tillers and slaughter machinery), military equipment (including tanks and troop carriers), and shipping equipment (pallets, bins, and containers).

Spray Virkon® S at 1% solution to disinfect and clean walls, ceilings, floors, decks, container surfaces, vehicles, wheels, water proof footwear (such as rubber boots), livestock equipment, utensils and instruments.

Do not immerse metal objects in Virkon® S for long periods - 10 minutes is maximum contact time.

DISINFECTION LIMITED TO SPECIFIC AND KNOWN DISEASE ORGANISMS

Not approved for this use in California

The instructions above call for use of a 1% solution for general disinfection, however, Virkon® S is effective against the following disease organisms at the dilution rates specified below. If the threat is known and limited to one of the organisms below, Virkon® S may be used at the following dilution rates:

| Disease Organism | Dilution rate | Oz./Gal. |
|-------------------|---------------|----------|
| PCV2 Virus (PMWS) | 1:200 | 0.7 |

USES IN FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS

A 1% solution of Virkon® S is recommended to clean and disinfect inanimate surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. Virkon® S may also be used to clean and disinfect equipment related to the maintenance of animals found at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.

To ensure that Virkon® S does not come in direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. To ensure precise application on inanimate surfaces, Virkon® S may only be applied using hand-held sprayers, sponges on other absorbent materials. Do not allow Virkon® S to pool on surfaces that may be within reach of animals. Do not allow Virkon® S to come into direct contact with people. Allow Virkon® S to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place in tightly closed container away from children. Always replace lid after use.

DISPOSAL: Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

E. I. DUPONT DE NEMOURS & COMPANY
DuPont Payment Services
P. O. Box 80040
Wilmington, DE 19880-0040

05/14/08

US GOVT
ENVIRONMENTAL PROTECTION AGENCY
1005 CONVENTION PLAZA SL-MO-C2-GL
GOVT LOCKBOX 979074
SAINT LOUIS, MO 63197

| DOCUMENT NO. | INVOICE NO. | DATE | GROSS | DISCOUNT | NET |
|--------------|-------------|----------|-------------|----------|-------------|
| 1707268517 | MM1013952 | 04/28/08 | 26,250.00 | 0.00 | 26,250.00 |
| TOTALS | | | \$26,250.00 | 0.00 | \$26,250.00 |

Questions regarding faster deposits through Electronic Funds Transfers, Please e-mail
DPS.Wilm@USA.Dupont.com; For payment questions, please e-mail AP2@USA.DuPont.com

Attachment
Check # 3000091457

THE FACE OF THIS CHECK IS PRINTED BLUE - THE BACK CONTAINS A SIMULATED WATERMARK



E. I. DUPONT DE NEMOURS & COMPANY
DuPont Payment Services
P. O. Box 80040
Wilmington, DE 19880-0040

No. 3000091457

62-20
311

PAY TO
THE ORDER OF

US GOVT
ENVIRONMENTAL PROTECTION AGENCY
1005 CONVENTION PLAZA SL-MO-C2-GL
GOVT LOCKBOX 979074
SAINT LOUIS, MO 63197

05/14/08

*****\$26,250.00

Twenty six thousand two hundred fifty and 00/100 Dollars

CITIBANK N.A.
A SUBSIDIARY OF CITICORP
ONE PENN'S WAY
NEW CASTLE, DE 19720

E. I. DuPont de Nemours & Company
DOO1



⑈ 3000091457 ⑈

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

May 7, 2008

Document Processing Center [REGFEE]
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Adam Heyward, PM 34

**SUBJECT: Virkon® S: (EPA Reg. No. 71564-6)
Application for Petition for Tolerance Exemption and Amended
Registration of a Registered Product
2008 PRIA Category A440 (First food use, establish tolerance exemption)**

Dear Mr. Heyward:

On behalf of E.I du Pont de Nemours and Company (DuPont), I am submitting a petition and an application for amended registration of their product, Virkon® S. Virkon® S contains the active ingredient, Potassium peroxymonosulfate.

There are existing registrations for this product. This will be the first food use for this chemical.

DuPont is submitting a petition and an amended registration for a new use for an old chemical. This registration is proposing the use of this chemical in poultry and swine premises. Application will not be made to the animals themselves, but the animals may be present when application is made.

The presently registered Virkon agricultural premise use does not permit application to be made when the poultry and swine are present. The animal presence during application makes the proposed use a food use and could require the submission of additional data. However, EPA has previously reviewed du Pont data to elucidate the nature of the residue data that could occur from the use. A letter from the U.S. EPA dated January 29, 2008, from Mr. Adam Heyward to Dr. Thomas McEntee, du Pont included an attachment dated 1/24/08 from Dr. William Hazel et al to Mr. Adam Heyward. The attachment stated, "that an exemption from the requirement of a tolerance appears to be appropriate for residues of potassium peroxymonosulfate and sodium chloride when applied to poultry premises when poultry are present".

The January 29 letter also states that, "the Agency has also considered data needs for all other disciplines including occupational/residential exposure, environmental fate, ecological effects, and toxicology. No additional data are necessary for any of these disciplines to support this proposed amended use or petition for exemption from the requirement of tolerances in eggs; poultry, meat; poultry, fat; and poultry, meat byproducts". We believe that this conclusion for poultry can also be extended to include swine. I am attaching a copy of the Agency communication and science review.

This amended registration and proposed tolerance exemption also includes a proposed exemption from the requirement of a tolerance for swine, meat; swine, fat; and swine, meat byproducts.

Enclosed please find the enclosed documents in support of this amended registration:

1. Petition for a tolerance exemptions for residues of potassium peroxymonosulfate and sodium chloride when applied to swine and poultry premises;
2. Amended Virkon[®] S registration for this new use for an old chemical;
3. Five copies of the Proposed Product Labels;
4. Certification with Respect to Citation of Data Form (EPA Form 8570-34);
5. Data Matrices (EPA Form 8570-35);
6. Copy of the EPA Letter from Mr. Heyward to DuPont and of the science review from Dr. William Hazel et al.
7. DuPont MSDS for Virkon[®] S, Revised 18-Aug-2006

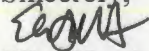
The data to support this petition has been reviewed by EPA and is in the MRID No. cited below:

Study Title: Ion Chromatographic and Iodometric Titration Studies of Test Substance H-26820, EPA Reg. No. 71654-6; MRID No. 47115101

This amendment and tolerance petition are subject to PRIA Category A440, with a \$26,250 fee and 21 months review period. Footnote 1 of the PRIA Pre-Pay Antimicrobial - Action Codes and Fee Table states that, "All uses (food and/or non-food) included in any original application or petition for a new active ingredient or a first food use that otherwise satisfy the conditions for the category are covered by the base fee for that application". Based on this, no additional fee is required to support the corresponding label amendment.

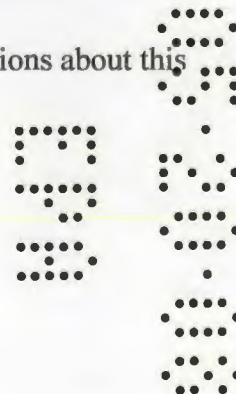
Thank you for your assistance with this application. If you have any questions about this submission, please call me at (202) 393-3903 ext. 14 or e-mail me at eharrison@lewisharrison.com.

Sincerely,



Eliot Harrison

E.I. du Pont de Nemours and Company



**EPA**

United States
Environmental Protection Agency
 Washington, DC 20460

- ☒ **Registration**
☐ **Amendment**
☐ **Other - Reregistration**

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|---|
| 1. Company/Product Number EPA Reg. No. 71654-6 | 2. EPA Product Manager Adam Heyward | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Virkon® S | PM# 34 | |
| 5. Name and Address of Applicant (Include ZIP Code) E.I. duPont de Nemours DuPont Chemical Solutions Enterprise P. O. Box 80402 Wilmington, De 19880-0402 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |

Section - II

- ☒ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application
☐ Notification - Explain below. ☒ Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. This is a petition for an exemption from the requirement of a tolerance and an amended registration for a new use on an old chemical. The registered label for livestock premises require that animals and poultry be removed from the premises during treatment. This submission and revised label permit swine and poultry to remain present during treatment.
2. Petition Fee:
 Requesting Antimicrobial First Food Use: Establish Tolerance Exemption
 Fee Category: A440. Fee: \$26,250
 Address PRIA questions to eharrison@lewisharrison.com

Section - III

| | | | | | |
|---|--|---|-------------------|--|---|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | <input type="checkbox"/> Metal | <input checked="" type="checkbox"/> Plastic |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt | No. per container |
| | | | | 1.3 oz. | 50 |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 10 lb., 4 lb., 1 lb., 9 oz. | | 5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | | | |

Section - IV

| | | |
|--|---|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) | | |
| Name Eliot Harrison, Lewis & Harrison 122 C St. NW, #740, Washington D.C. 20001 | Title: Agent for E. I. du Pont de Nemours and Company, DuPont Chemical Solutions Enterprise | Telephone No. (Include Area Code): (202) 393-3503 x.14 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title: Agent for E.I. duPont de Nemours, Dupont Chemical Solutions Enterprise | |
| 4. Typed Name: Eliot Harrison | 5. Date 5/7/08 | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Certification with Respect to Citation of Data

| | |
|--|----------------------------------|
| Applicant's/Registrant's Name, Address and Telephone Number E.I. duPont de Nemours and Company, DuPont Chemical Solutions Enterprise, P. O. Box 80402, Wilmington, DE 19880-0402. Tel: (302) 695-6856 | EPA Registration 71654-6 |
| Active Ingredient(s) and/or representative test compound(s): Potassium peroxymonosulfate | Date |
| General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Pets and domestic animals and their man-made premises | Product Name Virkon® S |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

- ☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

- ☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).
- ☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

- ☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

| | | |
|---------------|----------------|--|
| Signature | Date 5/7/08 | Typed or Printed Name and Title Eliot Harrison, Agent for E.I. du Pont de Nemours, DuPont Chemical Solutions Enterprise |
|---------------|----------------|--|



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

| Date April 24, 2008 | | | EPA Reg. No./File Symbol 71654-6 | | Page 1 of 4 |
|--|--|------------------|--|--------|-------------|
| Applicant's/Registrant's Name & Address: E.I. du Pont de Nemours and Company P.O. Box 80023, Wilmington DE 19880 | | | Product Virkon® S Disinfectant and Virucide | | |
| Ingredient(s): Potassium peroxymonosulfate (CAS # 70693-62-8); sodium chloride (CAS # 7647-14-5) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 830.1550 | Beginning Materials | 41057401 | A.H. Robbins | OLD | |
| 830.1600 | Description of Materials Used to Produce the Product | 41057401 | A.H. Robbins | OLD | |
| 830-1650/61-2 | Description of formulation process | 41057401 | A.H. Robins | OLD | |
| 830-1650/61-2 | Description of formulation process | 46166002 | DuPont | OWN | |
| 830-1670/61-3 | Discussion of formulation impurities | 41057401 | A.H. Robins | OLD | |
| 830.1700 | Preliminary Analysis | No MRID assigned | DuPont | OWN | |
| 830.1750 | Certified Limits | 46617503 | DuPont | OWN | |
| 830.1800/62-3 | Enforcement Analytical Method | 46617501 | DuPont | OWN | |
| 830.1800/62-3 | Enforcement Analytical Method | 41057401 | A.H. Robins | OLD | |
| 830.6302/63-2 | Color | 41057401 | A.H. Robins | OLD | |
| 830.6303/63-3 | Physical State | 41057401 | A.H. Robins | OLD | |
| 830.6304/63-4 | Odor | 41057401 | A.H. Robins | OLD | |
| 830.6314/63-14 | Oxidation/Reduction: Chemical Compatibility | 41057401 | A.H. Robins | OLD | |
| 830.6314/63-14 | Oxidation/Reduction: Chemical Compatibility | 46617502 | DuPont | | |
| 830.6315/63-15 | Flammability | NA | | | |
| 830.6316/63-16 | Explodability | NA | | | |
| 830.6317/63-17 | Storage Stability | 40439301 | DuPont | OWN | |
| 830.6317/63-17 | Storage Stability | 41057401 | A.H. Robins | OLD | |
| 830.6317/63-17 | Storage Stability | 42092401 | A.H. Robins | OLD | |
| 830.6317/63-17 | Storage Stability | 46943701 | DuPont | OWN | |

Signature

Name and Title:

Eliot I. Harrison, Consult to E.I. du Pont de Nemours

Date

April 24, 2008



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DATA MATRIX

| Date April 24, 2008 | | EPA Reg. No./File Symbol 71654-6 | | Page 2 of 4 | |
|--|--|--|--|-------------|------------------------|
| Applicant's/Registrant's Name & Address: E.I. du Pont de Nemours and Company P.O. Box 80023, Wilmington DE 19880 | | Product Virkon® S Disinfectant and Virucide | | | |
| Ingredient(s): Potassium peroxymonosulfate (CAS # 70693-62-8); sodium chloride (CAS # 7647-14-5) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 830.6320/63-20 | Corrosion Characteristics | 41057401 | A.H. Robins | OLD | |
| 830.6320/63-20 | Corrosion Characteristics | 46943701 | DuPont | OWN | |
| 830.7000 | pH | 46617502 | DuPont | OWN | |
| 830.7100/63-18 | Viscosity | NA | | | |
| 830.7300 | Bulk Density | 46617502 | DuPont | OWN | |
| 71-2 | Avian Acute Dietary: Bobwhite Quail | 00020457 | Dearborn | OLD | |
| 71-2 | Avian Acute Dietary: Mallard Duck | 00020458 | Dearborn | OLD | |
| 850.1400/72-4 | Fish ELS: Rainbow Trout & Bluegill Sunfish | 00019852 | Dearborn | OLD | |
| 850.1400/72-4 | Fish ELS: Sheepshead minnow | 47143401 | DuPont | OWN | |
| 870.1100/81-1 | Acute Oral Toxicity | 41057102 | A.H. Robins | OLD | |
| 870.1200/81-2 | Acute Dermal Toxicity | 41057103 | A.H. Robins | OLD | |
| 870.1300/81-3 | Acute Inhalation Toxicity | 41057104 | A.H. Robins | OLD | |
| 870.1300/81-3 | Acute Inhalation Toxicity | 42591201 | DuPont | OWN | |
| 870.2400/81-4 | Primary Eye Irritation | 41057105 | A.H. Robins | OLD | |
| 870.2400/81-4 | Primary Eye Irritation | 41057106 | A.H. Robins | OLD | |
| 870.2400/81-4 | Primary Eye Irritation | 44242001 | DuPont | OWN | |
| 870.2500/81-5 | Primary Dermal Irritation | 41057107 | A.H. Robins | OLD | |
| 870.2500/81-5 | Primary Dermal Irritation | 41057108 | A.H. Robins | OLD | |
| 870.2500/81-5 | Primary Dermal Irritation | 44242002 | DuPont | OWN | |
| 870.2600/81-6 | Skin Sensitization | 41057109 | A.H. Robins | OLD | |
| 82-1 | 90-Day Oral Toxicity | 00138801 | DuPont | OWN | |
| 82-4 | 90-Day Inhalation Toxicity | 00138806 | DuPont | OWN | |
| 84-2 | In vitro Mutagenicity Studies | 00138803 | DuPont | OWN | |
| Signature | | | Name and Title: Eliot I. Harrison, Consult to E.I. du Pont de Nemours | | Date April 24, 2008 |



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DATA MATRIX

| Date April 24, 2008 | | EPA Reg. No./File Symbol 71654-6 | | Page 3 of 4 | |
|--|--|--|-----------|-------------|------|
| Applicant's/Registrant's Name & Address: E.I. du Pont de Nemours and Company P.O. Box 80023, Wilmington DE 19880 | | Product Virkon® S Disinfectant and Virucide | | | |
| Ingredient(s): Potassium peroxymonosulfate (CAS # 70693-62-8); sodium chloride (CAS # 7647-14-5) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 91-2 | Efficacy | 41057410 | DuPont | OWN | |
| 91-2 | Efficacy | 45637101 | DuPont | OWN | |
| 91-2 | Efficacy: AOAC Use Dilution: <i>E. coli</i> , <i>K. pneumoniae</i> , <i>S. epidermidis</i> , <i>S. typhimurium</i> , <i>S. pyogenes</i> | 46166001 | DuPont | OWN | |
| 91-2 | Efficacy: AOAC Use Dilution: <i>S. aureus</i> , <i>S. choleraesuis</i> | 46166003 | DuPont | OWN | |
| 91-2 | Efficacy | 46166004 | DuPont | OWN | |
| 91-2 | Efficacy | 46166006 | DuPont | OWN | |
| 91-2 | Efficacy: AOAC Use Dilution: <i>L. monocytogenes</i> | 46166007 | DuPont | OWN | |
| 91-2 | Efficacy | 46166008 | DuPont | OWN | |
| 91-2 | Efficacy | 46166009 | DuPont | OWN | |
| 91-2 | Efficacy | 46166011 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: Virucidal: Porcine Circovirus | 46166019 | DuPont | OWN | |
| 91-2 | Efficacy: Virucidal: | 46265002 | | | |
| 810.2100/91-2 | Efficacy: Virucidal: Hepatitis A Virus | 46266201 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: Virucidal: Duck Hepatitis B Virus—Initial | 46266202 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: Virucidal: Duck Hepatitis B Virus—Confirmatory | 46266203 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: Virucidal: Bovine Viral Diarrhea Virus (BVDV)—Initial | 46266204 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: Virucidal: Bovine Viral | 46266205 | DuPont | OWN | |

Signature

Name and Title:

Eliot I. Harrison, Consult to E.I. du Pont de Nemours

Date

April 24, 2008



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DATA MATRIX

| Date April 24, 2008 | | EPA Reg. No./File Symbol 71654-6 | | Page 4 of 4 | |
|--|--|--|-----------|-------------|------|
| Applicant's/Registrant's Name & Address: E.I. du Pont de Nemours and Company P.O. Box 80023, Wilmington DE 19880 | | Product Virkon® S Disinfectant and Virucide | | | |
| Ingredient(s): Potassium peroxymonosulfate (CAS # 70693-62-8); sodium chloride (CAS # 7647-14-5) | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| | Diarrhea Virus (BVDV)—Confirmatory | | | | |
| 810.2100/91-2 | Efficacy: AOAC Use Dilution: <i>S. aureus</i> , MRSA | 46498601 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: AOAC Use Dilution: <i>E. faecalis</i> , VRE | 46498602 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: Nonfood Contact Sanitizer: <i>S. aureus</i> , <i>K. pneumoniae</i> | 46498603 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: AOAC Use Dilution: <i>E. Coli</i> O157:H7 | 46498604 | DuPont | OWN | |
| 91-2 | Efficacy: Feline Calcivirus | 46498605 | DuPont | OWN | |
| 91-2 | Efficacy: Feline Calcivirus | 46498606 | DuPont | OWN | |
| 91-2 | Efficacy: Respiratory Syncytial Virus (RSV) | 46498607 | DuPont | OWN | |
| 91-2 | Efficacy: Influenza A Virus | 46498608 | DuPont | OWN | |
| 91-2 | Efficacy: Avian Influenza (H3N2) Virus | 46808701 | DuPont | OWN | |
| 91-2 | Efficacy: AOAC Use Dilution | 46808702 | DuPont | OWN | |
| 91-2 | Efficacy: Fungicidal Use Dilution: <i>T. mentagrophytes</i> | 46983501 | DuPont | OWN | |
| 810.2100/91-2 | Efficacy: Tuberculocidal | 47071801 | DuPont | OWN | |
| Special Study | Ion Chromatographic and Iodometric Titration | 47115101 | DuPont | OWN | |

| | | |
|---------------|--|------------------------|
| Signature | Name and Title: Eliot I. Harrison, Consult to E.I. du Pont de Nemours | Date April 24, 2008 |
|---------------|--|------------------------|

